

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

4 JANSSEN PRODUCTS, L.P., CIVIL ACTION NUMBER:
PHARMA MAR. S.A..

5 Plaintiffs.

⁶ See also the discussion of the relationship between the two in the section on the "Economic Crisis."

7 EVENUS PHARMACEUTICALS
LABORATORIES, INC., HANGZHOU
VIA REACTE 2004
VIDEOCONFERENCE

REDACTED TRANSCRIPT

6 v.
7 EVENUS PHARMACEUTICALS
8 LABORATORIES, INC., JIANGSO
9 HENGRIU PHARMACEUTICALS
10 COMPANY, LTD., NATCO PHARMA
11 LTD SUN PHARMACEUTICAL
INDUSTRIES LTD., SUN
PHARMACEUTICAL INDUSTRIES
INC., FRESENIUS KABI USA,
LLC,

12 | Defendants.

13 Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
14 Trenton, New Jersey 08608
January 4, 2022
15 Commencing at 11:00 a.m.

A P P E A R A N C E S:

19 SAUL EWING ARNSTEIN & LEHR LLP
BY: CHARLES M. LIZZA, ESQUIRE
WILLIAM C. BATON, ESQUIRE
20 One Riverfront Plaza
Newark, NJ 07102
21 For the Plaintiffs

23 Megan McKay-Soule, Official Court Reporter
megansoule430@gmail.com
24 (215) 779-6437

25 Proceedings recorded by mechanical stenography; transcript produced by computer-aided transcription.

1 **A P P E A R A N C E S (Continued):**

2 KRAMER LEVIN NAFTALIS & FRANKEL LLP
3 BY: IRENA ROYZMAN, ESQUIRE
4 CHRISTINE WILLGOOS, ESQUIRE
5 DANIEL WILLIAMS, ESQUIRE
6 1177 Avenue of the Americas
7 New York, NY 10036
8 For the Plaintiffs

9 RIVKIN RADLER LLP
10 BY: GREGORY MILLER, ESQUIRE
11 25 Main Street, Suite 501
12 Court Plaza North
13 Hackensack, NJ 07601
14 For the Defendants

15 KNOBBE MARTENS
16 BY: WILLIAM ADAMS, ESQUIRE
17 KAREN CASSIDY, ESQUIRE
18 1155 Avenue of the Americas, 24th Floor
19 New York, NY 10036
20 For the Defendants

21 MIDLIGE RICHTER LLC
22 BY: JAMES S. RICHTER, ESQUIRE
23 645 Martinsville Road
24 Basking Ridge, NJ 07920
25 For the Defendants

26 WINSTON & STRAWN LLP
27 BY: IVAN POULLAOS, ESQUIRE
28 35 W. Wacker Drive
29 Chicago, IL 60601
30 For the Defendants

31 **ALSO PRESENT:**
32

33 Clara Jimenez, Esquire, Johnson & Johnson
34 William McGowan, Esquire, Johnson & Johnson

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1 (PROCEEDINGS held via Zoom videoconference before The
2 Honorable Zahid N. Quraishi, United States District Judge, on
3 January 4, 2020, at 11:00 a.m.)

4 THE COURT: Good morning, everybody. We're on the
5 record. Janssen Products v. eVenus, docket number 20-9369. I
6 know we're on the record and we're starting on time, so that's
7 always nice. One of the benefits of Zoom. I've got a few
8 housekeeping matters that I want to briefly chat about, but
9 let me get appearances first from plaintiff and then
10 defendants and then we'll go from there.

11 MR. LIZZA: Good morning, Your Honor. Pleasure to
12 appear before you for the first time. Charlie Lizza and Bill
13 Baton from the Saul Ewing firm on behalf of Janssen and Pharma
14 Mar. And my co-counsel will introduce themselves as well.

15 THE COURT: Good to see you, guys, Mr. Lizza and Mr.
16 Baton.

17 MS. ROYZMAN: Your Honor, good morning and happy New
18 Year. Irena Royzman from Kramer Levin representing Janssen
19 and Pharma Mar. And with me is Christine Willgoos, also of
20 Kramer Levin, and Daniel Williams, also Kramer Levin.

21 THE COURT: Good morning and happy New Year to you
22 guys as well.

23 MS. ROYZMAN: We also have two client representatives
24 on the conference, Clara Jimenez, litigation counsel at
25 Johnson & Johnson, as well as William McGowan, counsel at

1 Johnson & Johnson.

2 THE COURT: Great. Good morning.

3 Who's going to be speaking on behalf of the plaintiff
4 today, or is it multiple people?

5 MS. ROYZMAN: It will be two people, Your Honor.

6 It'll be myself and it'll be Dan Williams, an associate at the
7 firm.

8 THE COURT: Okay. Great. Good morning to everybody
9 on that side.

10 Let me hear from defense.

11 MR. MILLER: Good morning, Your Honor. Gregory
12 Miller, Rivkin Radler, on behalf of the Sun Natco defendants.
13 And with me today from the Knobbe Martens firm we have William
14 Adams and Karen Cassidy, and Mr. Adams will be taking the lead
15 for us today.

16 THE COURT: Good morning, to all of you.

17 MR. RICHTER: Good morning, Your Honor. James
18 Richter of Midlige Richter on behalf of the eVenus, Fresenius,
19 and Hengrui defendants, and with me on the call today is Ivan
20 Poullaos from Winston & Strawn.

21 MR. POULLAOS: Good morning, Your Honor.

22 THE COURT: Good morning. Good morning, Mr.
23 Poullaos.

24 Mr. Richter, who's speaking on your end?

25 MR. RICHTER: So, Your Honor, we don't anticipate any

1 -- of us speaking today.

2 THE COURT: Okay. That makes it even easier.

3 So let me ask you this then. Let me ask this from the
4 plaintiffs' side first. I just want to get a sense of what's
5 being done today. I got the briefs. I've got the
6 demonstrative, the deck or the slides, and I've reviewed
7 those. What do you anticipate presenting today, or are you
8 just going over the slides?

9 MS. ROYZMAN: I think, Your Honor, it's -- our
10 thought was it's whatever is helpful to you, but we are
11 prepared to present our technology tutorial as well as to give
12 more substance and body to the slides that Your Honor has
13 reviewed.

14 THE COURT: Okay. That would be helpful. There's no
15 witnesses or anything like that from your end, correct?

16 MS. ROYZMAN: No. No, there are not.

17 THE COURT: Mr. Adams, is that the same on your end?

18 MR. ADAMS: It is, Your Honor. I think what the
19 parties did before this call was to meet, confer, and talk
20 about sort of the presentation today to make sure we're all on
21 the same page. We've done that. I think the parties agreed
22 to a certain time limit and the order. And I think the idea
23 is really to just add more body to what you have in front of
24 you already.

25 THE COURT: That will be helpful for me.

1 What is that timing? Just so I have a sense of it,
2 too. Ms. Royzman, from your end, how long are you
3 anticipating? I don't have a clock so you have my time, but
4 I'm just curious as to how much time you anticipate you're
5 going to be today.

6 MS. ROYZMAN: Your Honor, I think for the tech
7 tutorial as well as the claim construction analysis we
8 anticipate 45-to-50 minutes. And then, of course, you know,
9 time for Your Honor's questions during or after the
10 presentation as well as any -- as well as any rebuttal. But
11 what we had discussed with Mr. Adams and the Natco defendants
12 is that plaintiffs, again subject to your preference, would go
13 first and present their arguments.

14 THE COURT: I think that makes sense.

15 Mr. Adams, that's something that you guys have agreed
16 to? Do you have a similar time frame, 45, 50 minutes on your
17 end?

18 MR. ADAMS: We do, Your Honor. We did agree to that.
19 I think the concept is plaintiffs go first with their tech
20 tutorial as well as their argument. We will respond with our
21 presentation. I think the time frame will be about the same,
22 45-to-50 minutes, something like that. And then, you know,
23 obviously subject to your questions, Your Honor, if you have
24 questions during the presentation you might go over at the
25 end. However you prefer to do it we're certainly able to do

1 that.

2 THE COURT: Okay. I'll tell you from my perspective
3 what I will likely do, and so I might as well give you a
4 heads-up now, is I think after both your presentations, unless
5 something strikes me during the presentation where I need to
6 interrupt you with a question, what I'm likely to do is to
7 temporarily adjourn for about 30 minutes when both your
8 presentations are complete. I'll want to get my thoughts
9 together with my notes, and then I'm going to come back on and
10 to the extent I have any additional questions, I'll pose them
11 then. If I don't have any additional questions ^ , then I'll
12 adjourn us for the day. Does that work for everybody? I'm
13 going to break for about 30 minutes so I can collect my
14 thoughts after both presentations and circle back to you.
15 Does that work for you, Ms. Royzman?

16 MS. ROYZMAN: It does. We weren't planning to do
17 rebuttal because we're going to go first.

18 THE COURT: I'll give you that opportunity as well
19 then.

20 Let me ask you all this. Are you guys going to work
21 through? I don't eat lunch, so I'm deferring to all of you on
22 whether you plan to work through or do you need me to break so
23 you all can, I don't know, grab a sandwich or whatever it is
24 that you may want to do?

25 MR. ADAMS: I think in terms of my preference, Your

1 Honor, I'm certainly happy to work through. I think it makes
2 a lot of sense in terms of efficiency and timing and for Your
3 Honor's own timing. And so I think from our perspective going
4 through as we agreed with what plaintiffs going through each
5 side's preparation, and then like you said, if you take your
6 adjournment and come back, I think that would probably be a
7 good natural break for us to take anyway.

8 THE COURT: Ms. Royzman, does that work for your end?
9 I'll give you all one. I just didn't know what the
10 expectation was from counsel.

11 MS. ROYZMAN: I think a ten-minute break, something
12 along those lines would be helpful.

13 THE COURT: Do you guys want it before your rebuttal?
14 Where do you want me to do that? It's a little after 11:00,
15 so I'm just trying to get a sense of do you want to let me
16 know where you want to break, or do you want to break before
17 you do a rebuttal and then I'll break at the end of that? You
18 tell me.

19 MS. ROYZMAN: I think before the rebuttal would be
20 very helpful.

21 THE COURT: Any objection there, Mr. Adams? I don't
22 see why there would be.

23 MR. ADAMS: There's not, Your Honor.

24 THE COURT: I'll hear from the plaintiffs. I'll hear
25 from defendants. We'll take a brief break, maybe ten minutes

1 or so, and, Ms. Royzman, you can tell me then how much you
2 will need and that's fine. We'll take a break for everybody
3 and then jump back on for rebuttal. And then I'll break
4 again, but for a little bit longer, maybe 20, 30 minutes just
5 so I can collect my thoughts. I think that makes sense.

6 What else? Anything more from the plaintiff before we
7 start? You guys can walk me through this. No.

8 MS. ROYZMAN: No, thank you.

9 THE COURT: Mr. Adams, anything on your end?

10 MR. ADAMS: One comment. I think that plaintiffs are
11 reserving time for rebuttal. We would ask the same thing in
12 terms of the rebuttal. We at least get an opportunity to hear
13 that and respond if there is a response. So we would ask for
14 that as well.

15 THE COURT: Ms. Royzman, how long is this rebuttal
16 that you're anticipating? You know what the arguments are
17 going to be, so I'm just trying to get a sense from you. It's
18 not like Mr. Adams is going to bring up something shocking
19 here from his side. He's already briefed it.

20 MS. ROYZMAN: I think the rebuttal will be short,
21 Your Honor. It depends on the argument, but I imagine it will
22 be short.

23 THE COURT: Mr. Adams, I have no objection to hearing
24 from you, but I'm not going to go back and forth. I'm not
25 going to do surrebuttal and sur-replies and all the rest of

1 it. If you both want one opportunity for rebuttal, and Mr.
2 Adams, if you want to briefly address it, I don't see any
3 reason why I should prohibit that, but at some point we need
4 to end. Does that work for everybody?

5 MR. ADAMS: It does, Your Honor. Thank you.

6 THE COURT: I don't have anything more. This is
7 probably the most you're going to hear from me today. So I'm
8 going to turn it over to.

9 I have the deck slides from both of you, but I was
10 going to look at a hard copy. Are you going to be needing me
11 to look at anything on the screen? I'm right now set up on a
12 laptop. I don't have a dual monitor. I have a dual monitor
13 on my left, but does it matter how I'm reviewing this, Ms.
14 Royzman?

15 MS. ROYZMAN: I don't think it does. I was going to
16 share the slides, so would that allow you to see them?

17 THE COURT: I'm on a single monitor, but I have the
18 slides in hard copy. So if you refer to the slides by page, I
19 can easily follow you. I have them literally right in front
20 of me. Does that work for everybody? Only because I'm
21 concerned that I'd have to reboot on to my desktop with two
22 monitors for me to be able to see the documents, unless you
23 want to test it out briefly.

24 MS. ROYZMAN: Let's test it out. I think we'll be
25 okay, Your Honor.

1 THE COURT: Okay. I see all of you, but I don't see
2 the document.

3 MS. ROYZMAN: Sorry, Your Honor.

4 THE COURT: That's all right. Let's just test it out
5 now.

6 MS. ROYZMAN: Here we go.

7 THE COURT: I have no problem with you sharing the
8 slides on the screen as well. I may take notes on my hard
9 copy, but does that work for everybody? I can see everyone so
10 I don't have any technical issues on my end.

11 MR. ADAMS: It works for defendants, Your Honor. I
12 think what we'll try to do is to say slide numbers as we talk.

13 THE COURT: If you guys don't mind doing that, I'll
14 be watching, but because I have a hard copy in front of me, I
15 prefer to -- I'm old school. I like to handwrite on paper, so
16 it will be useful if you can refer to the slides by page, and
17 if somehow I lose you, I may ask you or interrupt you just to
18 remind me of where we are. Okay?

19 MS. ROYZMAN: That sounds good, Your Honor.

20 So Dan Williams, an associate at the firm, is going to
21 present our technology tutorial. So I will hand it over to
22 Dan.

23 THE COURT: Thank you.

24 MR. WILLIAMS: Good morning, Your Honor.

25 THE COURT: Good morning, Mr. Williams.

1 MR. WILLIAMS: The patent before you, the '557
2 patent, covers pharmaceutical formulations of trabectedin.
3 Trabectedin is also known as ET-743.

4 This case is about the defendants' generic copies of a
5 drug named Yondelis®. Here we'll refer to Natco's generic
6 version of Yondelis® as Natco's ANDA product. So if you look
7 at slide 2. Yondelis® is a lifesaving cancer drug developed
8 by Pharma Mar and Janssen that treats specific types of rare
9 soft tissue cancer that were difficult to treat. In the
10 decades prior to Yondelis® there were no promising new therapy
11 options for the patients with these rare soft tissue cancers
12 when conventional treatment options failed.

13 In 2015, the FDA approved Yondelis® and it has been
14 marketed by Janssen in the United States ever since.

15 An essential aspect to bringing Yondelis® to the market
16 on a commercial scale is the ability to store the product for
17 long periods of time at refrigerated temperatures and without
18 any major degradation of the product. It is the unique
19 formulation for trabectedin that made it possible to
20 commercialize Yondelis®, and it's that unique formulation for
21 Yondelis®. That is what the '557 is all about.

22 If you look at slide 3, generally speaking,
23 pharmaceutical products can be administered to patients in a
24 variety of different ways. For example, drugs can be ingested
25 orally. For example, they can be formulated as tablets or

1 capsules that can be swallowed. They can be formulated as a
2 product that can be injected. They can be formulated as a
3 topical product that can be applied to the surface of the
4 skin, eyes, or ears, or they can be formulated as something
5 that can be inhaled.

6 Yondelis® was formulated as a lyophilized injectable
7 drug, which means that the formulation is freeze-dried into a
8 dry cake for purposes of storage, and then it's later
9 re-liquified just prior to using it to treat a patient.

10 If you turn to slide 4, please.

11 When we say "formulation," we're referring to the
12 mixture of ingredients that make up the drug product. All
13 drug formulations have an active ingredient. This is the
14 active substance of the drug product and is often referred to
15 as the active pharmaceutical ingredient or API of the drug
16 product. It is the thing that causes the desired
17 pharmaceutical effect in the patient. Most often drug
18 products also have inactive ingredients, which are typically
19 present to help deliver the active substance.

20 If you turn to slide 5, please.

21 Some drug products have just one active ingredient
22 while others can have multiple active ingredients. It is very
23 easy to tell how many active ingredients there are in a drug
24 product. This can be readily determined by simply looking to
25 the prescribing information or the packaging.

1 As you can see here, Yondelis®, on the far left, has
2 one active ingredient and that is trabectedin. Other drugs
3 can have more than one active ingredient, but again, the
4 number of active ingredients can be clearly determined by just
5 looking at the packaging. If you look in the middle,
6 Biktarvy® has three active ingredients and on the right
7 Symtuza® is a drug that has four active ingredients.

8 If you turn to slide 6, please.

9 As I mentioned, Yondelis® has one active substance; it
10 is trabectedin. This is abundantly clear by simply looking to
11 the product label or the prescribing information as you can
12 see on the left.

13 If you turn to slide 7, please.

14 Yondelis® also has several inactive ingredients, which
15 we've highlighted for you here on the slide.

16 Turn to slide 8, please.

17 Impurities are unwanted things that end up in the final
18 product. As you can see on this slide, there are many
19 different types of impurities. For example, there can be
20 metal impurities from the manufacturing equipment used to make
21 the drug. Other examples include impurities that arise from
22 the preparation of the active ingredient or its degradation in
23 the formulation. The bottom line is that all drug products
24 inevitably contain some kind of impurity. It is completely
25 expected.

1 If you can turn to slide 9, please.

2 The fact that all drugs contain some kind of impurities
3 is a fact that is agreed by both sets of parties in this case.
4 Here we have plaintiffs' Dr. Cory Berkland on the left as well
5 as Natco's Executive Vice President of Research and
6 Development, Dr. Pulla Reddy, on the right, testifying to that
7 fact.

8 Unless you have any further questions, Your Honor, I'll
9 pass the presentation over to my colleague, Ms. Irena Royzman.

10 THE COURT: You know what, maybe just one, Mr.
11 Williams, and this just comes out of ignorance. When you talk
12 about the packaging of the active ingredients, is that a
13 requirement for a pharmaceutical packaging that the active
14 ingredient is always identified on the package, or were you
15 just showing me three examples in which that was done,
16 including your drug?

17 MR. WILLIAMS: I believe it's required. I don't know
18 that I can make a hard representation, but it's my
19 understanding that that's what you have to do is put the
20 active ingredient on the packaging. I think it might be a
21 requirement by the FDA, but I'm not a hundred percent certain.
22 But those three examples clearly show that the packaging lists
23 the active ingredient. I believe that to be the case for all
24 drugs on the market in the U.S.

25 THE COURT: Okay. Thank you.

1 MR. WILLIAMS: Thank you, Your Honor.

2 MS. ROYZMAN: Your Honor, and I second that. That
3 is, -- those were just exemplary. That's always the case; the
4 active is on the label and on the packaging. It has to be
5 identified.

6 Okay. '557 patent. As Dan Williams described, the
7 patent protects trabectedin formulations. Prior art
8 formulations were unstable and had high levels of these
9 undesired impurities, and the patented formulations stabilize
10 the active ET-743 and reduce impurities. All the generic
11 manufacturers involved in this case and in the related MSN
12 case that's also pending before Your Honor copied the patented
13 formulations exactly. They're very useful.

14 The summary of the invention for the patent says the
15 present invention provides ET-743 compositions, which comprise
16 ET-743, the active, and the disaccharide the -- an inactive
17 ingredient. The patent explains that ET-743 formulations face
18 the problem of relatively large amounts of impurities and
19 these impurities are produced during the lyophilization
20 process and during storage of the formulation. And the patent
21 also explains that ET-701 is the main impurity.

22 Because of that, the patent sets forth a specific goal,
23 and the specific object of this invention is to provide new
24 stable formulations of ET-743. And the inventors discovered
25 that use of certain inactive ingredients, certain

1 disaccharides as bulking agents can drastically reduce the
2 formation of impurities and also allowed the product to be
3 stored at refrigeration temperatures, as Dan Williams
4 described.

5 Now, all the formulations that are exemplified and
6 described in the patent are ET-743 formulations. And there
7 are 22 of them and we have pulled them out for Your Honor.
8 These are tables in the patent and we have highlighted in
9 green all the examples of ET-743 formulations and these are
10 the only formulations. And ET-743 is the active in all of
11 them and the other ingredients are inactives.

12 One of the formulations on that list in table XVI is
13 referred to ET-NF-G. That's the preferred form ET-743
14 formulations and described as such in the patent. And the
15 composition is -- of that formulation is set forth and it
16 matches exactly with that of Yondelis®, which is to your right
17 on slide 16, Your Honor, and they are -- they are an exact --
18 they are an exact match.

19 On slide 17 the patent also explains that all of the
20 ET-743 formulations, "embodiments of formulations according to
21 this invention," this is text from the patent, have
22 impurities, have potential impurities, and these include
23 ET-701, ET-745 and other impurities.

24 So what's the claim construction issue with that
25 background? So the -- this is a representative claim. There

1 are two independent claims, claim 1 and claim 22, and -- and
2 the claim is to lyophilize the anti-tumor composition where it
3 has an active and it has inactives and a certain beneficial
4 effect: the reduction of ET-701 impurities. And the dispute
5 is with respect to one term: a single active anti-tumor
6 compound. So the dispute is with respect to the active of the
7 composition. Only Natco has sought construction of this term.
8 None of the other defendants have.

9 What are the parties' constructions?

10 THE COURT: I know you make that point, but it's not
11 dispositive. Is your point behind that, hey, Judge, if there
12 was any real argument here, all the defendants would support
13 Natco's construction theory? Is that the point of that?

14 MS. ROYZMAN: That's one of the points, and -- but
15 also, Your Honor, the term is just clear. And all the other
16 defendants have the same to gain and this is -- and they are
17 not comfortable making this argument and are not joining this
18 argument that Natco is presenting here.

19 THE COURT: Ms. Royzman, just so I understand the
20 plaintiffs' perspective on this, you have an alternative
21 argument. You're not asking the Court to find that the claim
22 term should be interpreted as single compound providing the
23 anti-tumor activity of the composition. What you're saying is
24 the plain and ordinary meaning should apply. That's the
25 primary argument of the plaintiff, correct?

1 MS. ROYZMAN: Yes, Your Honor. So one of the
2 disputes that has arisen is Natco says plain and ordinary
3 meaning, you can't do that here because there's a dispute and
4 the Court has to resolve the dispute. And we agree that the
5 Court has to resolve the parties' dispute. But the Court can
6 do that simply by rejecting Natco's position and adopting the
7 plain and ordinary meaning of these very simple words: a
8 single anti-tumor compound.

9 In the alternative, if the Court wants to construe the
10 term, then we think it should be construed with its plain and
11 ordinary meaning of an active. The single compound providing
12 the active anti-tumor activity of the composition. There's no
13 dispute between the parties as to single or compound. It all
14 comes down to this active anti-tumor. And in our view, it's
15 critical for active not to be written out and not to be taken
16 out of the claim. And Natco's construction, as you'll see in
17 a moment and as you've seen in our briefing, does that.

18 So the meaning of the claim term is clear. As we've
19 already discussed, the other defendants didn't seek
20 construction. MSN has already stipulated to infringement of
21 the patent under the plain and ordinary meaning. Natco, in
22 its paragraph IV certification, which is what started off this
23 litigation, never challenged infringement, never asserted the
24 type of claim construction that it is now. And it's -- now
25 construction is driven by an incorrect non-infringement

1 theory.

2 Now, another dispute that's before the parties and that
3 Natco raised in the -- in its reply brief is whether the Court
4 can consider the accused device as part of its analysis. And
5 the Federal Circuit precedent makes very clear -- and we had
6 discussed this in our opening brief as well as our proposed
7 reply brief that was filed last week -- but the case law makes
8 very clear. And, in fact, the Federal Circuit has emphasized
9 the importance of the context provided by an analysis of the
10 accused device when ruling on claim construction and the
11 problems presented by construing claims in a vacuum in the
12 absence of such context. That just makes sense. The Court
13 should be educated and have an understanding of the
14 implications of its ruling.

15 And, again, this is *Typhoon* in 2011, the Federal
16 Circuit says: It's not inappropriate for a court to consider
17 the accused device when construing claim terms, for the
18 purpose of claim construction is to resolve issues of
19 infringement.

20 Natco has cited *Wilson Sporting Goods* to Your Honor.
21 And as discussed in our proposed reply brief, and this was
22 also in our opening brief, *Wilson Sporting Goods* stands for
23 the proposition that context is extremely important. There,
24 both sets of parties deprived the Court of any context. They
25 failed to provide the court with any information about the

1 accused device, and the Federal Circuit said that doesn't
2 work. The accused device provides meaningful context and the
3 court shouldn't be deciding claim construction in a vacuum.
4 So, in fact, what *Wilson Sporting Goods* -- what occurred in
5 *Wilson Sporting Goods* and what it stands for is that the
6 accused device is important in the analysis. It can't supply
7 claim limitations, but it's very important for it to be
8 considered. And the Federal Circuit remanded the case back to
9 the District Court in order to consider claim construction in
10 the context of the accused device.

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 The other fallacy of Natco's construction and why it's
16 not even helpful to Natco in the first place is because

17 [REDACTED]

18 How do we know that? Just like Natco has to identify its
19 active to FDA, it has to identify its impurities because FDA
20 wants to know what the patient is getting. And that
21 identification of impurities is [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

1 [REDACTED] That's it. And so Natco is
2 ultimately not helped by its incorrect claim construction
3 position.

4 With respect to ET-701, Natco changed its position. It
5 now concedes that [REDACTED]

6 [REDACTED] and it's the main impurity that's described in
7 the '557 patent, is expressly excluded by the plain language
8 of the claims from being an active anti-tumor compound. We
9 agree. ET-701 makes very clear that the claims permit
10 impurities and that impurities are not active anti-tumor
11 compounds.

12 So Natco's, in sum, the construction's incorrect and
13 premised on -- entirely premised on an incorrect theory.
14 Natco now admits correctly that ET-701, an impurity, is not an
15 active anti-tumor [REDACTED]

16 [REDACTED]
17 [REDACTED] And Natco filed a
18 reply brief to -- to Your Honor arguing something different
19 [REDACTED] And we had
20 -- I think it's DI-181 -- submitted a proposed reply brief to
21 Your Honor that again addresses this and [REDACTED]

22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

25 So now the claim construction analysis, because I think

1 at this point Your Honor has the full background of what the
2 parties are disputing and the context for the dispute.

3 So *Phillips*, Federal Circuit 2005 en banc, is an
4 important Federal Circuit case that provides guidance to the
5 courts as to how to conduct a claim construction analysis.
6 And it provides a hierarchy of evidence that the court is to
7 consider. And first it discusses the intrinsic evidence.
8 There are three types. The claims, the specification, and the
9 prosecution history. And *Phillips* says claims are the most
10 important. That's where you look first because they set the
11 metes and bounds of what, you know, of what's covered, what's
12 protected. Then it's the specification and the construction
13 that's in line with the specification is typically the correct
14 construction.

15 Prosecution history is third in line because as the
16 Federal Circuit explains, again in *Phillips*, it's the product,
17 the back-and-forth with the patent office. So it doesn't have
18 the same clarity as a final integrated document the way the
19 claims and specification do.

20 And then below the intrinsic evidence is extrinsic
21 evidence and the asterisks are there because it's far below.
22 And understand extrinsic evidence, like dictionaries and
23 articles and expert testimony, they can be helpful. They can
24 provide background. Courts rely on them, but they have to be
25 consistent with the intrinsic evidence and they can't

1 contradict it.

2 So let's start with the claims as *Phillips* instructs.

3 So first we look to the claims. And the claims here are very
4 instructive. The claims say this is a lyophilized anti-tumor
5 composition that has a single active anti-tumor compound. How
6 do we have an anti-tumor composition? It's because of the
7 single active anti-tumor compound.

8 The claims also tell us what that compound is. It's
9 ET-743. This is a lyophilized ET-743 formulation. And they
10 also tell us that there's a benefit to this formulation, and
11 that benefit is that there is less conversion of ET-743 into
12 ET-701. It's less than 2% ET-770. So if you have a higher
13 percentage, you're outside of this claim.

14 So what does the claim teach? ET-743 is the single
15 active. ET-743 provides the activity of the composition.
16 That's how we have an anti-tumor composition. And ET-701 is
17 an impurity. It's clearly not an active anti-tumor compound.

18 The Federal Circuit in *Phillips* and in lots of cases
19 has made clear when construing patent terms there's a heavy
20 presumption that the language in the claim carries its
21 ordinary and customary meaning, and we have very simple
22 language here: a single anti-tumor compound.

23 Here is Dr. Berkland talking -- speaking to what that
24 plain and ordinary meaning is, which comes off -- right off
25 the claims and is consistent with the specification and

1 everything else. But he's saying that a person of ordinary
2 skill in the art would understand the term to be the single
3 compound providing the anti-tumor activity of the composition.

4 It's the active.

5 So let's look at this specification, Your Honor.

6 Again, following the hierarchy set forth by *Phillips*. So the
7 specification, and *Phillips* points out, it's usually
8 dispositive. It's the single best guide to the meaning of a
9 disputed term. The construction should be consistent with the
10 specification.

11 Again, the summary of the invention. Present invention
12 is ET-743 compositions. They comprise inactive ET-743 and
13 disaccharide, inactives. In summary, all examples are ET-743
14 formulations. There are 22 formulations that are exemplified.
15 They have ET-743 as the only active. Patent makes very clear
16 that ET-NF-G, one of those 22, is the preferred ET-743
17 formulation. There are no formulations with any other active
18 that are exemplified. And all ET-743 formulations have
19 potential impurities. The patent makes that clear, and ET-701
20 is the main one. And we looked at this evidence before, but
21 slide 40 shows those 22 ET-743 formulations. Slide 41 focuses
22 on ET-NF-G. And again, that's the preferred formulation and
23 the formulation of Yondelis®. The patent makes very clear
24 that formulation ET-NF-G is a preferred formulation; that text
25 is right there.

1 Slide 43, immediately after saying that that
2 formulation is preferred, the specification says embodiments
3 of formulations, according to this invention, they were
4 tested, and they all have impurities or potential impurities,
5 including ET-701 and ET-745 and other impurities and they're
6 below a certain level. So all the examples have potential
7 impurities. That's what the patent teaches.

8 And again, ET-701, as we saw, is the main one. And
9 again, a construction that encompasses the embodiments and
10 stays true to the claim language will then be the correct
11 construction. And that's the case here.

12 There's the prosecution history, Your Honor. Again,
13 third in line, according to *Phillips*. So the prosecution
14 history can limit the meaning of terms, but -- but the court
15 must give claim language its presumptive ordinary meaning,
16 limited solely by the patentee's clear and unmistakable
17 disclaimer. And there's no disclaimer here, contrary to
18 Natco's arguments of impurities, which all ET-743 formulations
19 at some level have.

20 So before we get into the details of the prosecution
21 history, at a high level what happens is there's a rejection
22 over a prior art reference by the patent office. That
23 reference is called Faircloth, and in response to that
24 rejection applicants narrow their claims to specifically say
25 that they will have a single active anti-tumor compound. And

1 the reason that that happened is they were being rejected over
2 a formulation that, in the examiner's view, was a combination
3 product. It had multiple actives so it looked like -- you
4 think back to the technology tutorial that Dan Williams
5 presented -- it looked like Symtuza® or Biktarvy®. It had
6 multiple actives. And so in order to distinguish it,
7 applicants explained that that's -- that's not what we're
8 claiming. Here, our claims are directed to a single active
9 anti-tumor compound where that active is ET-743. So it's not
10 to these combo products.

11 So again, here's the rejection, and the patent office
12 is saying that here we may have a formulation where you have
13 two drugs in the same composition: kahalalide F and ET-743.

14 And in slide 49, in responding to that rejection,
15 applicants say, well, we've amended our claims and now we say
16 our compositions, they're not to multiple actives. They
17 consist of a single active anti-tumor compound, which is
18 ET-743. Therefore, our claims don't encompass combinations of
19 kahalalide F and ET-743, if that's what Faircloth were to
20 describe. And then they do it again. It's not two
21 combinations of anti-tumor compounds.

22 Now, when you provide an amendment to the patent
23 office, you have to provide support for your language. And
24 that's exactly what applicants did. And looking at this
25 support is very helpful because, again, it's instructive as to

1 both the meaning of the terms and what was actually given up
2 versus what wasn't. And here, the amendment is supported and
3 the language of the amendment is above by a paragraph that
4 refers to the ratio of active substance to bulking agents. So
5 applicants are providing support for the word "active." And
6 we'll look at that in a second. But basically they're
7 equating active with active versus inactive so the active
8 ingredient.

9 In addition -- and this was just cut for brevity --
10 there's additional support about how drugs can be administered
11 separately and so they don't have to be part of the same
12 composition. That supported the construction. And then in
13 addition, the examples of the application disclosed
14 compositions, and we looked at all of them, there are 22, in
15 which ET-743 is the only active anti-tumor compound.

16 Here is that paragraph. Again, it's equating active
17 substance with active compound. This is the active of the
18 composition and here is the further support for the claim
19 amendment which makes -- because, again, applicants relied on
20 all of the examples, and the patent makes clear that the
21 examples have potential impurities, including ET-701 and
22 ET-745. And so these are not being treated as actives in the
23 prosecution history. To the contrary, applicants said these
24 examples have a single active; it's ET-743. That's correct.
25 These are impurities and they're permitted.

1 So here's the sum-up, but it's everything we've
2 discussed. The claims were amended to recite a single active
3 anti-tumor compound. That claim amendment was supported by a
4 discussion of the active anti-tumor compound as the active
5 substance, active ingredient of the composition. The claim
6 amendment was supported with examples of the specification,
7 all of which have ET-743 as the only active and all of which
8 have impurities. ET-743 formulations with impurities were not
9 disclaimed. Just the opposite. They were the support for the
10 claim amendment. What did applicants give up? They gave up
11 combo products along the lines of Symtuza® and Biktarvy®,
12 products with combinations of actives, multiple drugs.

13 And again, the case law is very clear, any disclaimer
14 is -- it's congruent with the scope of the surrender. You
15 only surrender what you surrender, not more.

16 The extrinsic evidence here illustrates a couple of
17 things. One, contrary to arguments being presented here and
18 testimony cited, Natco knows what an active is. It -- it's a
19 thing and it's a thing in every drug product and it has to be
20 identified [REDACTED]

21 [REDACTED] Why did it do that? Because it's true.

22 [REDACTED] Why
23 did it do that? Because it's true.

24 [REDACTED] It's
25 trabectedin. It's identified.

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 Now, Natco's construction is incorrect for a lot of
16 reasons. It disregards the claim. It reads out "active."
17 Can't do that. It injects ambiguity into the claims. It
18 completely contradicts the specification. It disregards the
19 disclosure. It ignores that all the embodiments have
20 potential impurities. Natco's construction reads every
21 embodiment of the invention out of every claim of the patent.
22 It's leading the Court into error. It's not supported. It
23 mischaracterizes the prosecution history.

24 So again, here's the claim. Claim is very clear. It
25 requires an active anti-tumor compound. That active

1 anti-tumor compound is ET-743 and ET-701. An impurity is even
2 expressly mentioned in the claims. Impurities by no means are
3 disclaimed.

4 Contrary to the claims, Natco's construction attempts,
5 through its possessing properties, to include potential
6 impurities as active anti-tumor compounds when they're not.
7 The claims made clear what the active is. They make clear
8 what provides the activity of the composition, and impurities
9 are expressly permitted.

10 The other fallacy here is that -- and again, as Dan
11 Williams pointed out in the technology tutorial, impurities
12 are inevitable. We're stuck with them. The FDA requires you
13 to identify them, and that's because every single drug product
14 on the market has impurities. Yondelis® and Natco's proposed
15 generic ANDA product is no different. Impurities at some
16 level are inevitable. And the courts understand that. And
17 this case, *Allergan v. Teva*, this is a decision actually by
18 Judge Bryson of the Federal Circuit, sitting by designation in
19 the Eastern District of Texas. He actually relied in that
20 case on the testimony of Dr. Berkland in connection with
21 impurities, the same Dr. Berkland whose testimony we have
22 cited here, including with respect to this undisputed issue.

23 In the real world -- and this is Judge Bryson -- in the
24 real world, impurities are inevitable. Therefore -- and he
25 explains, you know, you have trace amounts of impurities and

1 that any characterization of a pharmaceutical product in a
2 patent claim must be assumed to include impurities, unless
3 it's very clearly prohibited of all such impurities. And here
4 the claims are the opposite. They recite -- they expressly
5 recite the main impurity. They're not prohibited. Again, a
6 useful decision from a Federal Circuit judge sitting by
7 designation.

8 Here is a Federal Circuit opinion. Again, impurities
9 normally associated with a component of a claim are implicitly
10 adopted by the ordinary meaning of the components themselves.
11 And in these cases -- and going back to slide 66 -- you know,
12 defendants argue that somehow they have a non-infringement
13 position based on impurities. In this particular case, the
14 language was -- I think cyclosporin A is the only peptide and
15 is the only peptide present. And so defendants, Teva there,
16 tried to argue, well, so we have any impurities whatsoever,
17 any peptide impurities. We're outside the [REDACTED]

18 [REDACTED]
19 [REDACTED] And Judge Bryson said no. And the Federal
20 Circuit doesn't -- again recognizes that impurities are
21 inevitable.

22 Okay. So a major error in Natco's construction, and
23 again, because it's focused on alleged impurities, is to read
24 out "active." That's what it does. It takes out the word
25 "active." You no longer have an active and that's clear

1 error.

2 And *Vederi* is an example of a case where the court says
3 by effectively reading out a claim term, I think substantially
4 there, that the district court erred. It took out claim
5 language.

6 Natco's construction also makes the claims less clear.
7 This is not supposed to be an exercise -- or claim
8 construction. It's not supposed to be an exercise that's
9 unhelpful. It's supposed to resolve the parties' disputes,
10 but it's not supposed to make the claims less clear or
11 introduce ambiguities where there are none. And here, what
12 properties and in what setting? Clearly, Natco is not focused
13 on the setting of the lyophilized composition, the setting of
14 the claim. It's not interested in that because it's relying
15 on alleged impurities, which are not active.

16 This is Dr. Berkland noting that Natco's construction
17 is confusing to a person of ordinary skill. And again, as
18 this -- as this district has found in another case involving
19 Sun, construction that only serves that vagueness isn't
20 helpful and isn't the right way to go. So Natco's
21 construction is contrary to the claims and injects ambiguity.
22 It's wrong.

23 Natco also does violence to the specification. It
24 disregards that all the examples are ET-743 formulations. It
25 actually pretends that ET-743, ET-NF-G is not the preferred

1 ET-743 formulation when the patent says it is. And there are
2 no formulations with any other active. And all ET-743
3 formulations have potential impurities. So -- and those are
4 not actives. ET-701 is just the main one.

5 Again, every example is an ET-743 example. Every
6 example has potential impurities.

7 The courts, in case after case, and we cited many on
8 this point, normally do not interpret claim terms in a way
9 that excludes disclosed examples in the specification.
10 Verizon on slide 77 is one such example, but that's not what
11 courts do. And here, Natco is asking the Court to read out
12 every embodiment from every claim in the patent. It's asking,
13 through its incorrect claim construction, for the patent to
14 cover nothing, not to protect its ET-743 formulations, which
15 all of the generics copied. It's asking for the Court to turn
16 the patent into a nullity contrary to well-established law.
17 This is clearer error. Natco ignores, again, the preferred
18 ET-743 formulation. It's the commercial embodiment.
19 Claim interpretation that excludes a preferred
20 embodiment, again, is rarely, if ever, correct. Here the
21 problem is far worse than that, and the claim interpretation
22 that excludes the inventor's device is rarely the correct
23 interpretation. Again, that makes sense. The idea is not for
24 a patent to be a complete nullity. Natco's construction is
25 contrary to the specification. It's just flatly wrong.

1 As to the prosecution history, Natco claims that
2 somehow impurities were -- were disclaimed. In ET-743
3 formulations, ET-745 and others are potential impurities,
4 ET-701. They're not disclaimed. They were -- they were the
5 support for -- for the amendment. Its -- its interpretation
6 of the prosecution history is completely incorrect.

7 The claim amendment, here it is. They added a single
8 anti-tumor compound. That anti-tumor compound is ET-743.
9 They equate it. Active anti-tumor compound with active
10 substance. It's -- it's a claim with a lyophilized anti-tumor
11 composition that has one active, and it certainly allows
12 impurities and, in fact, expressly recites the main one.

13 So again, Natco ignores the support, the support that
14 tells us, that makes crystal, that the impurities in ET-743
15 formulations are not disclaimed.

16 Again, it relies on the examples as support, and all
17 the examples have impurities.

18 The law is very clear. We -- courts must give claim
19 language its presumptive full ordinary meaning, limited solely
20 by the patentee's clear and unmistakable disclaimer. And
21 there's no disclaimer of ET-743 lyophilized compositions with
22 impurities. Those are the support for the claims.

23 Natco's construction is contrary to the prosecution
24 history. Natco's construction is also incorrect. And it
25 spends a lot of time, I think it submits many extrinsic

1 articles to Your Honor, and they have various studies about
2 how to synthesize certain things and that they test ET-770 or
3 ET-745 outside of the relevant context. The relevant context
4 is ET-743 formulations. That's what the claims concern. The
5 claims are ET-743 formulations. Those formulations, if ET-770
6 or ET-745 are [REDACTED]

7 [REDACTED]
8 [REDACTED] The patent tells us that. And so this barrage of
9 references is really completely irrelevant. It doesn't
10 support a construction -- the construction that Natco is
11 advocating.

12 So Natco's construction has no support in any of the
13 evidence, intrinsic or extrinsic, and really it leads the
14 Court into error, and so we ask for the Court to resolve the
15 dispute by rejecting Natco's construction and to adopt the
16 plain and ordinary meaning of these very, very simple words.
17 And to the extent the Court decides to or determines to
18 construe the term, that the Court construe it in accordance
19 with its ordinary meaning: the compound providing the
20 anti-tumor activity of the composition.

21 Thank you, Your Honor.

22 THE COURT: Thank you, Ms. Royzman.

23 Mr. Adams, do you want to take a minute, or do we
24 need a break? You tell me. How do you guys want to proceed?
25 Do you guys want five or ten minutes before we switch to

1 defendants' position?

2 MR. ADAMS: Your Honor, unless you want to take a
3 break, I'm fine going forward right now.

4 THE COURT: Okay. Let me reboot. Just give me a
5 moment. I'm ready to proceed then if you guys don't want to
6 take a break. We'll do what we said initially which is break
7 after Mr. Adams presents.

8 MR. ADAMS: Your Honor, I can share my screen as well
9 and walk through the slide deck. I know you have a hard copy
10 there.

11 THE COURT: It was helpful, though, to have my notes
12 written here while you referred to the slides even by page.
13 Although, I will tell you, it's not hard to follow. If you
14 don't mind sharing the screen, as Ms. Royzman did, and I'll
15 view the screen and write in front of me.

16 MR. ADAMS: Okay.

17 MS. ROYZMAN: Good. You're set.

18 THE COURT: Yes, I can see it.

19 MR. ADAMS: Okay, great. Thank you, Your Honor.

20 So William Adams, again, from Knobbe Martens for the
21 Sun and Natco defendants.

22 I really just want to start with a little background on
23 Sun and Natco. Sun and Natco are both global pharmaceutical
24 companies. They do both branded and generic side work across
25 the globe.

1 Before I get into a tech tutorial, I know Your Honor
2 has heard a lot about the technology, so I'll try to make this
3 as efficient as possible and not retread a lot of the stuff
4 you just heard, or obviously what you have in front of you in
5 the briefing.

6 Before I jump into the tech tutorial, I really want to
7 talk about sort of how we got here, and I titled this slide 3
8 in front of you Claim Construction Posture. You did hear a
9 lot about this concept of Natco's ANDA product and Your Honor
10 asked a regulatory question about what's supposed to be on the
11 label. There's a lot of discussion in plaintiffs' briefing
12 about Natco's product or their own product or the accused
13 product or regulatory questions of the impurity levels and how
14 much in identifying those and how do you do that and Dr.
15 Reddy's testimony.

16 What is very apparent from the Federal Circuit case law
17 is looking at accused product to try to read in a claim
18 limitation, which is exactly what Natco -- which is exactly
19 what plaintiffs are doing, is improper. The Federal Circuit
20 said that over and over and over again. So that much we know
21 is true. What you do is if you step back for a minute you
22 think about how we got here because it's very apparent what
23 plaintiffs are doing. Plaintiffs have walked through our
24 accused product with it in hand and reread the claims. You
25 just heard from plaintiffs' counsel this concept of this claim

1 term is very clear. And the plain meaning is the word on the
2 page. But then they have an alternative plain meaning, so
3 apparently there's two plain meanings. And that's where I
4 think the confusion sets in. And if you step back for a
5 minute and walk through how we got here, it starts to become
6 very clear.

7 Earlier in this case defendants served their
8 infringement and invalidity contentions. We put forth our
9 non-infringement position. Plaintiffs responded to that, and
10 that response is very apparent. Plaintiffs are reading this
11 plain meaning of single active anti-tumor compound very
12 differently than we are. And so the parties obviously went
13 through with claim construction exchanges.

14 One of the things I want to point out, I know
15 Magistrate Judge Goodman ruled on this allowed plaintiffs to
16 later on amend their construction to add this new alternative
17 proposal, but the local rules expressly require you to provide
18 on the due day a simultaneous exchange of the plain meaning.
19 We did that. We said here's our construction. Plaintiffs
20 didn't do that. They said plain meaning. That's it. That's
21 in violation of local rule 4.2.

22 But the point there, Your Honor, is this concept of
23 them taking what we gave them, they take our construction,
24 they take our evidence we gave them. For weeks they
25 re-reviewed our non-infringement contentions. They met,

1 conferred with us, and out of that process popped out this new
2 alternative plain meaning, which we talk about in our briefing
3 and obviously now in our tutorial here. That construction
4 cannot be correct. And that construction, more importantly,
5 is based on this concept of looking at the accused product to
6 really go back to the keyboard and rewrite the claim. So
7 again, the Federal Circuit has told us over and over and over
8 again that's improper.

9 And so what we really are left with under the Federal
10 Circuit case level to my peril is there is a dispute here.
11 That dispute needs to be resolved, and whether the ultimate
12 construction is plain meaning means the word on the page,
13 whether plain meaning means defendants' construction, it
14 simply cannot be that the plain meaning is this alternative
15 new construction that plaintiffs come up with.

16 So again, I'm going to try not to rehash a lot of the
17 tutorial, but what I do want to do is talk a little about the
18 background of these ecteinascidin or ET compounds. So the
19 '557 was first filed from a priority filing in 2004. If we go
20 back decades before that, what was well-known in the art, what
21 were these ET compounds. In fact, they were discovered
22 decades before, going back to 1969. And then six of those, at
23 least six of those were isolated and identified by 1986.
24 Again, the '557 patent was filed in 2004, so we're talking
25 about a long time before that patent was filed. And what you

1 see in front of you is a discussion of that and really the
2 concept of identifying these ET compounds was to understand
3 what their utility was. Were they compounds that could be
4 used for anticancer compounds. So back to 1986, scientists
5 identified six of these. Of those were ET-743, which you've
6 heard a lot about today, ET-745, and ET-770, among some other
7 ones.

8 And so when you really -- when you go back and you look
9 at the big picture from 1986 to 1990, scientists were working
10 on these to see what their value was, their utility. And what
11 the Rinehart publication tells us here -- again, this is prior
12 art 15 years before the '557 patent was even filed -- that
13 scientists by this time had identified and isolated, had
14 tested and had understood that these compounds, including 743,
15 745 and 770, were potent anti-tumor agents. So that's --
16 you'll see this kind of go on and on as you walk through these
17 slides. But what happened was scientists understood these a
18 long time before we got to the patent. When you get to the
19 patent, which I have in front of you, slide 6 here, the
20 background of the patent starts talking about, again, these ET
21 compounds and calling them a promising new class of anticancer
22 agents.

23 So that's one concept I want to make sure we all
24 understand. There's a lot -- they want to discuss about
25 impurities, but what needs to be understood too is scientists

1 well before the filing of the '557 patent, the inventors of
2 the '557 patent all understood that these ET compounds,
3 including ET-743, ET-745, ET-770 and others were, in fact,
4 active anti-tumor compounds. They all understood that. That
5 was disclosed in the background of the patent.

6 Now the other concept I want to talk about in the
7 patent is what was the invention here? What was the alleged
8 invention? And so when you get to the '557 patent, by that
9 time it really -- there's a lot in the art, and this is a very
10 long prosecution history. But there's a lot in the prior art
11 that talked about formulations or compositions of these ET
12 compounds. And what was well-known then was there were
13 stability issues with these and so they needed to be
14 lyophilized. Lyophilized means really putting them in a
15 powder form that can then be reconstituted and then injected.
16 So with that framework, again, the sea of prior art that
17 disclosed ET compounds alone and what's known as a mannitol or
18 a monosaccharide, ET compounds with a second or third or
19 additional anti-tumor compounds with a disaccharide in the
20 composition, which we saw a moment ago in the Faircloth
21 reference, those were all in the prior art.

22 So in view of that sea of prior art, that's when we get
23 to what was eventually allowed in these claims. And these
24 claims are, you know, narrowly drafted to cover specific
25 lyophilization compositions.

1 What you see in front of you here on slide 8 is this,
2 you know, lyophilized anti-tumor composition. It comprises
3 several things. One of those is a single active anti-tumor
4 compound. And then another one is a disaccharide. It lists
5 specific disaccharides that can be used. And one of the
6 points I want to make here to take away from these claims is
7 these aren't -- these aren't method of treatment claims.
8 These are composition claims. These are -- if you think for a
9 minute, Your Honor, you're in your kitchen, you have a recipe.
10 That's what these are. These are a formulation. You put some
11 disaccharide in there. There's sucrose or lactose. You put a
12 compound in there and that's the composition. There's also no
13 specific quantity amount required of a single active
14 anti-tumor compound. It simply needs to be one and only
15 active anti-tumor compound. That's it. And so that's the
16 framework of these claims. They aren't, again, method of
17 treatment claims. There is no requirement or limitation about
18 how much single active anti-tumor compound needs to be present
19 here.

20 But then the prosecution history, while I'll talk about
21 a little bit more detail today, you heard some already, what
22 happened here is a long prosecution history that has to do
23 with two parts here. One is the single active anti-tumor
24 compound we've been talking about. As you know, in view of
25 the Faircloth reference, kahalalide F plus ETF -- ET-743, the

1 patentees need to limit the construction or limit the claims
2 to a single active anti-tumor compound.

3 The other part here that wasn't discussed much is this
4 entire alleged invention -- and this is years of prosecution
5 history -- was all about getting around the prior art using
6 disaccharide with a specific amount of it -- with disaccharide
7 to ensure that you had an impurity level of 701, which is a
8 different limitation in the claim, needed to be below a
9 certain amount. And that was required, again, to get these
10 claims allowed. The patentees obviously understood that
11 ET-701 was the impurity that they were concerned with, and
12 that was written into the claims. You've heard a lot about
13 active anti-tumor compound and ET-701 and impurities. ET-701
14 is a different limitation of the claim. Active anti-tumor
15 compound is not discussing ET-701. It's -- the patentees
16 dealt with that. The examiner understood that. That was in
17 front of the examiner when the single active anti-tumor
18 compound language was added to the claim. That's a different
19 limitation. We aren't here today to talk about the limitation
20 of 2% ET-701 after storage. That isn't under claim
21 construction. Single active anti-tumor compound is what we're
22 here to talk about today.

23 So that takes us to the disputed term, which
24 defendants' construction, single compound possessing
25 anti-tumor properties, is really the plain meaning. It's --

1 when you look at it in the context of the extrinsic record, it
2 really has support -- the extrinsic record we cite to supports
3 the concept of these anti-tumor compounds having these
4 properties, which gives them this activity such that they are
5 active anti-tumor compounds.

6 Now, when you look at plaintiffs' construction here,
7 and, again, what we've heard numerous times is the term
8 doesn't need to be construed because it has a plain meaning,
9 but if you're going to construe it, the plain meaning in this
10 long construction, the single compound providing the
11 anti-tumor activity of the composition. It's a mouthful
12 because it's a rewrite of the claim with a bunch of new words
13 that have no support in the intrinsic record. And really this
14 whole concept of this rewrite, as you've seen in the briefing,
15 as you've heard already today, and as you'll see in our
16 presentation is really focused on -- improperly focused on the
17 accused product, used in the accused product it's called
18 extrinsic evidence to rewrite the claim.

19 So here on slide 11 I'll just show you where the single
20 active anti-tumor compound shows up. It's in both independent
21 claims 1 and 2.

22 So let's start with the intrinsic record. The
23 intrinsic record supports defendants' construction. We'll
24 walk through the claim specification and prosecution history.
25 Picking up here, it starts with the claims. The claims --

1 when we start thinking about single active anti-tumor
2 compound, let's talk about single for a minute. Single means
3 one; one and only one. It doesn't mean additional one. And
4 it seems like at this stage plaintiffs appear to agree, as
5 they stated in their opening brief, single means one. And
6 that's supported by the claims themselves.

7 The other part of the term, active anti-tumor compound,
8 it really is -- you have to step back for a minute and think
9 about what does active anti-tumor compound mean? What is it
10 doing? And it really -- what it means is the active
11 anti-tumor properties of that compound is what gives it this
12 anti-tumor ability. So it's the anti-tumor properties of a
13 compound that makes it quote, active against tumors. What
14 you'll see a lot as we walk through the specification and as
15 we walk through the publications over and over again from the
16 scientists, including Pharma Mar, they talk about this concept
17 of testing these compounds. They use IC₅₀ data. They use in
18 vitro data. They use in vivo data where they test cell lines
19 in mice and they test against carcinoma and breast cancer and
20 all these different types of cancers. And what that is is the
21 properties of those compounds that have activity against
22 different cell lines. Sometimes, as Your Honor's probably
23 very aware, there are some compounds that have activity
24 against one type of cancer and they may not have activity
25 against another type of cancer. But it's that testing, it's

1 that in vitro data, that in vivo data that you see over and
2 over again in the intrinsic record, again in the extrinsic
3 evidence that we cite that is -- it's the properties of that
4 compound. Again, it's a single active anti-tumor compound.
5 Really that compound, it's something you would put into a
6 formulation that would be in a formulation and it possesses
7 those properties.

8 Again, what I point out here too is there's no quantity
9 requirement of this single active anti-tumor compound in these
10 independent claims. Even if you say single active anti-tumor
11 compound and where the active anti-tumor compound is 743, it
12 doesn't say how much you have to have, right? It could be .1
13 milligrams. It could be 10 milligrams. It could be 1
14 milligram. The point is it's present. It's a compound. It's
15 a thing, a noun that's present in this composition.

16 Now, if we turn to the specification, the patent
17 specification overwhelmingly supports defendants' construction
18 here. And really if you think about single compound
19 possessing anti-tumor properties and look at ET-743, just use
20 that as an example because I think everyone agrees that is an
21 active anti-tumor compound and does possess these anti-tumor
22 properties. The specification says ET-743 possesses potent
23 antineoplastic activity. Again, it's a variety of human tumor
24 xenografts grown in mice against these different types of
25 cancer, cancer cell lines.

1 Really what that means is -- antineoplastic means that
2 it blocks the formation of these neoplasms or growths that may
3 become cancer. So when you're thinking about the property of
4 this compound, ET-743, that is a property of it. It blocks
5 the growth of this. That is, again, what gives it this
6 anti-tumor activity in those specific -- in those mice against
7 those specific melanoma, ovarian, and breast cancer. And just
8 so you understand, Your Honor, human tumors, xenografts, are
9 really taking these cells, these growths and -- from humans
10 and grafting them, in this case, into mice. Again, it's those
11 properties that ET-743 has that gives it this anti-tumor
12 activity.

13 And I think Dr. Berkland, plaintiffs' own expert, would
14 agree with this. In fact, when asked at deposition what makes
15 ET-743 an active anti-tumor compound, it has been shown to
16 have this antineoplastic activity in several cancers, and he
17 it responded, citing to the same section of the patent
18 specification that I just put on the previous slide, slide 16,
19 column 2, and he says that, therefore, this claim to a
20 lyophilized anti-tumor compound has those properties. ET-743
21 has antineoplastic activity and, therefore, it has those
22 properties. That's, again, consistent with plaintiffs' --
23 with defendants' construction here.

24 The other part that I think has been missed here and
25 was really not mentioned in plaintiffs' presentation, but I

1 think it's very important, is the inventors of the '557 patent
2 and all the prior art that led up to that, they weren't only
3 concerned with ET-743. They said their invention is
4 applicable to other ecteinascidins or other ET compounds. And
5 what they said specifically is those ET compounds are
6 preferred, those other ones are preferred. For example, what
7 you see on slide 20 here is a quote right from the patent
8 specification: Thus, preferred compounds of this invention
9 include. And the top left compound you see is ET-743.

10 But what you see on the bottom right, and you didn't
11 hear mentioned earlier this morning, is ET-745 is, in fact, a
12 preferred compound of this invention. It just so happened
13 ET-743 was one of those and that's what led to the claims
14 here. But another preferred compound that would be an active
15 anti-tumor compound is ET-745. It's not only a compound, it's
16 not only an active anti-tumor compound, it's a potent active
17 anti-tumor compound that was preferred by the inventors
18 themselves. And what you see on slide 21 is just another
19 example from the patent specification where the inventors have
20 that preferred compounds of the invention include these ET-745
21 and 770 compounds.

22 THE COURT: Mr. Adams, let me ask you a quick
23 question about that, only because I'm looking at my notes
24 from, I think, the briefing, but I could be mistaken. I
25 thought it was in your briefing that at one point you had

1 mentioned that ET-745 and ET-770 were identified as
2 particularly preferred, but when I look at the chart, ET-770
3 isn't there and ET-745 is identified simply as preferred, not
4 particularly preferred. Is there an inconsistency there, or
5 am I looking at the wrong citation? Is that in your briefing?

6 MR. ADAMS: I don't know that -- if we said
7 "particularly preferred," I think that language is used in the
8 patent and other places. If we said that, "particularly
9 preferred," we misstated that, but I don't think we did. I
10 think what we said was "preferred compounds." And so when
11 these patents are written, basically -- a lot of times you
12 have a broad disclosure. You write a bunch of stuff in there
13 and then you start really narrowing it down to what they
14 believe is going to be their invention. Right? In this case,
15 when you start saying "preferred embodiments" or "preferred
16 compounds," these are the ones you think work. Right? So to
17 answer your question, Your Honor, if we wrote "particularly
18 preferred," I think we were misstating that.

19 THE COURT: That's all right. I want to make sure.
20 In 770, where is 770 identified?

21 MR. ADAMS: It's identified here on slide 21. It's
22 the second compound.

23 THE COURT: Okay.

24 MR. ADAMS: Slide 21.

25 THE COURT: Got it. I'm looking at slide 20, but

1 it's in slide 21 that 770 is identified.

2 MR. ADAMS: Yeah. Your Honor, what you see is a long
3 discussion in the background of 745 and 770, and then you keep
4 going in the patent and you see they're narrowing it down.
5 They don't talk about 729, but they talk about 745 and 770 as
6 being these preferred compounds.

7 THE COURT: Okay. I didn't mean to interrupt. I
8 just wanted to clarify that. I think I got it. Yep. Go
9 ahead.

10 MR. ADAMS: Now, plaintiffs are arguing that
11 defendants' construction somehow reads out these preferred
12 embodiments of the patent, and they keep saying 22 examples
13 and every example is read out by our construction. I think
14 that's wrong at least for three reasons. First of all, our
15 construction of single active anti-tumor compound, we don't
16 believe it reads out every embodiment. In fact, our
17 construction is really focused on the phrase "single active
18 anti-tumor compound" and what that means given the intrinsic
19 record. ET-743 is still present in the claim. That's an
20 additional statement in the claim. We've never said single
21 active anti-tumor compound doesn't cover ET-743. And that's
22 in the examples in the patent.

23 And then if you look at the impurity, what plaintiffs
24 call the main impurity, but it's the only impurity they
25 actually tested. In every single example, all the data they

1 showed you, every single example was about ET-701 as the
2 impurity. And it makes sense because that was really what
3 this alleged invention was about is trying to minimize ET-701.
4 And so every example has ET-743 and ET-701. And again, our
5 construction is single active anti-tumor compound and we're
6 not construing ET-701. That's a different limitation. And we
7 realized that and we say that's already accounted for in the
8 claim. That's a separate limitation. That limitation was in
9 front of the patent examiner when this language "single active
10 anti-tumor compound" was added. So our construction -- our
11 construction doesn't read out those embodiments. But even if
12 it did, even if it did, what plaintiffs ignore is the Federal
13 Circuit case law saying there are times when preferred
14 embodiments or other illustrative embodiments can be read out
15 when you're construing claims. And that's because you see
16 here in the *Helmsderfer* case that courts cannot rewrite claim
17 language. And if so, if it results in an embodiment, one or
18 more embodiments being read out, that's because that's the way
19 the claims are written, not because that's the way we read it
20 under our construction.

21 The other point I want to make in that is you saw a lot
22 of slides, I think three or four slides, if I counted
23 correctly, about ET-NF-G, this preferred formulation. Then
24 you saw in that same slide, over and over again, a quote from
25 column 27 of the patent that talks about ET-745. What never

1 happens in this patent, and what I think is not really being
2 shown correctly, is there are no formulations or compositions
3 shown in this patent that just show ET-745 being present as an
4 impurity. And even if there were, even if there's language in
5 column 27 that talks about maybe some embodiments had ET-745
6 present, that doesn't mean that every single embodiment, or
7 even the preferred embodiments had ET-745 present as an
8 impurity. Certainly, there's never any evidence that ET-NF-G,
9 the preferred composition they keep talking about, had
10 anything other than ET-701 and 743 present. That's the only
11 two ET compounds that were ever talked about in the context of
12 that formulation. If you look at the table, table 8, if you
13 look at figure 8 and 9, those all show ET-743 purity and
14 ET-701. That's it. Nothing more.

15 And then the additional point I want to make is that
16 the claims you have cover all embodiments. Again, if there is
17 an embodiment that has some other impurity or some other
18 compound present there, if this construction -- defendants'
19 correct construction is applied and there is an embodiment
20 that is not covered, and we don't think there is, but if that
21 were true, it doesn't matter. The Federal Circuit tells us
22 that a claim doesn't need to cover every single embodiment.
23 The patentee here clearly knew how to write a claim that said
24 we have a single active anti-tumor compound. We have 743 in
25 there and then we have this ET-701 impurity and we know how to

1 write the claim and we want to minimize this. That was the
2 whole goal of the patent itself. Minimize the amount of
3 ET-701. And that's in the claim.

4 So then the third reason I want to present that we're
5 not reading out preferred embodiments, and if we are, it's not
6 us doing it. It's really a reflection of the file history.
7 The prosecution history here was the place. It wasn't in the
8 claim originally. It wasn't in the specification. The
9 prosecution history was the place single active anti-tumor
10 compound first -- is the genesis of it, first evolved. It was
11 in that prosecution history, you've already seen numerous
12 times today, that that language was added. And the Federal
13 Circuit told us we have previously explained that limitations
14 may be construed to exclude a preferred embodiment if the
15 prosecution history compels such a result. And that's exactly
16 what is happening here. If any preferred embodiment, or any
17 embodiment in this patent is being read out, and it's our
18 position that it's not, but if it were, it's really based on
19 that prosecution history.

20 And so if we go to slide 23 here, on the screen in
21 front of you, we see the original claims. The original claim
22 was ET composition, which comprises ET-743 and a disaccharide.
23 As Your Honor saw earlier this morning, you know that it was
24 rejected over the Faircloth reference. And Faircloth is a
25 prior reference that disclosed kahalalide out. So that's an

1 active anti-tumor compound. It disclosed ET-743. And it
2 disclosed them together in a composition with a disaccharide.
3 So the examiner looked at these claims and said, well, you
4 have one active ET-743. You have a second active kahalalide
5 and a disaccharide. So your claim, as written, doesn't
6 exclude that. It's part of that claim. It would be within
7 the scope of that claim, so I'm going to reject, if you
8 anticipate it. What I think it's important to note in that is
9 there's no amount of ET-743 present in that Faircloth
10 reference. It's just that it was present. ET-743 was the
11 second one and kahalalide F is the other active anti-tumor
12 compound that was present. So again, it was the presence of
13 multiple active anti-tumor compounds that was the basis for
14 this rejection.

15 And that rejection then led us to a claim amendment and
16 this claim amendment was the addition of single active
17 anti-tumor compound. And in view of that, the applicants,
18 they made a claim amendment and then they made the argument.
19 I think what's important to note here is that if we look at
20 the bottom paragraph on what's slide 26 in front of Your
21 Honor, in addition to making the amendment, the applicants
22 argue that applicant claims would not encompass combinations
23 of anti-tumor compounds. So they didn't say in that scope
24 that you could have, you know, one compound that's at some
25 level and then you can have another one. But they said

1 clearly would not encompass combinations of anti-tumor
2 compounds. And the other point here is that they didn't say
3 active anti-tumor compounds because active and anti-tumor kind
4 of really means the same thing. If a compound isn't active,
5 it's not going to be an anti-tumor compound if it's not active
6 against the tumor. They know that. That's why it says active
7 anti-tumor compound and right here is it says anti-tumor
8 compound. They're really one in the same.

9 So in view of that intrinsic record, in view of the
10 claims and the specification and in view of the prosecution
11 history, which is clear on its face, is that this can only be
12 limited to a single compound. We think our construction is
13 correct that we put forth in this case.

14 In addition to that, if you look at the extrinsic
15 evidence, the extrinsic evidence that defendants cite
16 overwhelmingly supports this concept of this active anti-tumor
17 compound having these properties, possessing these properties,
18 these anti-tumor properties. And I don't want to go really
19 deep into this because it gets a little bit scientific and
20 complex in nature, but what I want to point Your Honor to is,
21 again, this Rinehart reference we talked about 1990. The
22 identification of these compounds, and then studying them, to
23 understand their potent anti-tumor agents. That included 743,
24 745 and 770. And you'll see at the bottom an IC₅₀ number
25 versus L210. And then you see a semicolon and another test

1 there. What that is, Your Honor, is really testing of these
2 compounds, that's ET-745 we've highlighted, but it's testing
3 of these compounds to see if they have these properties of the
4 anti-tumor activity, to see if they can inhibit the growth, to
5 see if they are an in vitro cell test, if they are inhibitory
6 of the cell growth, and see if they shrink tumors. Those are
7 the properties that make these anti-tumor compounds.

8 Again, in 2001, again, this is before the patent was
9 even filed, ET-770, again, has another example of being a
10 potent cytotoxic activity testing IC data against breast
11 cancer cells and carcinoma cells. And this theme just
12 continues, Pharma Mar on slide 29 here, again, saying that
13 ET-745 is a potent antiproliferative activity against a
14 variety of tumor cells. Even more recent we see this again on
15 ET-770. So this theme of these compounds possessing these
16 anti-tumor properties, it was in the prior art, Pharma Mar
17 published on it in the prior art. It goes to the background
18 of the patent. These become preferred compounds of the patent
19 itself. The inventors clearly knew these anti-tumor compounds
20 had these anti-tumor properties. And, in fact, again, they
21 said they were preferred in the context of the patent.

22 So that takes us to defendants' construction in view of
23 the intrinsic record and the extrinsic evidence that
24 overwhelmingly supports that these compounds have anti-tumor
25 properties. Defendants' construction is single compound

1 possessing anti-tumor properties.

2 On the other hand, what we have here on slide 31 is
3 plaintiffs' construction. Again, a single compound providing
4 the anti-tumor activity and the composition, this is clearly a
5 claim rewrite that really has no support in the intrinsic
6 record.

7 If we go to slide 32. Again, we look at *Phillips*
8 because *Phillips* is really the Federal Circuit telling us how
9 to do claim construction. We look at the intrinsic record and
10 the prosecution history. And then we can also look at the
11 intrinsic evidence, and *Phillips* tells us, it's less reliable
12 than the patent and its prosecution history. And generally
13 what you see is extrinsic evidence, things like dictionaries
14 or expert testimony or publications in the art at a relevant
15 time. What's not listed in there -- and I think this is an
16 important point -- is accused products, accused devices.
17 They're not extrinsic evidence. You cannot use accused
18 products to write in limitations. Federal Circuit has told us
19 that many times. This concept of using over and over again,
20 you know, as context, I think is, you know, when you do that
21 80 percent of the briefing and 90 percent of the exhibits, I
22 think that's a bridge too far for context. I think it's gone
23 to the point of writing in new limitations. And that's
24 exactly what we see here. Plaintiffs' construction is a claim
25 where you're rewriting by looking at the accused product.

1 On slide 33: Claims may not be construed with
2 reference to the accused product. That's *Wilson Sporting*
3 *Goods* from the Federal Circuit telling us that.

4 And then even more importantly, the accused product are
5 processed as a form of extrinsic evidence to supply
6 limitations for patent claim language. Yet -- that's, again,
7 *Wilson Sporting Goods* from the Federal Circuit. Yet, in this
8 case plaintiffs argued -- this is from the responsive brief
9 docket 171 at 14 -- plaintiffs argued that the only extrinsic
10 evidence relevant to this Court's claim construction analysis
11 is Natco's representation regarding its ANDA product.

12 So plaintiffs are arguing that in spite of what the
13 Federal Circuit told us, they're arguing that the only
14 extrinsic evidence is the accused product. Again, it's not
15 even extrinsic evidence.

16 So I think what comes from that is all this argument
17 and focus, well, what's in Natco's product. Oh, that's an
18 impurity. That can't be right. I think really when you step
19 back here for a minute, plaintiffs have it backwards. They're
20 improperly looking at the product until they come up with a
21 construction. And notably, the disputed phrase "single active
22 anti-tumor compound," it doesn't use the term "impurity" nor
23 do any parties' construction. Plaintiffs aren't providing
24 construction that use the word "impurity." Yet the entire
25 discussion is about what's in our product. Right? Looking at

1 an infringement issue, that's for the experts down the road.
2 That's for trial. That's not for claim construction. And
3 whether or not ET-745 or 770 are, quote, anti-tumor compounds
4 is not really a question for claim construction. The patent
5 says they are. The inventors believe they are. In fact, they
6 were preferred compounds of the invention. The prior
7 overwhelmingly says they are, but that doesn't really -- isn't
8 really part of the claim construction inquiry. The claim
9 construction inquiry is about what is the term "single active
10 anti-tumor compound," not what's in Natco's product.

11 So again, I think if you go to slide 36 here, Your
12 Honor, again, you've see this slide before, but it's -- it's
13 really highlighting the fact that ET-745 is a preferred
14 compound at the invention.

15 So I think where that takes us to, Your Honor, is
16 really this major focus on our product, first of all, is
17 wrong. We pointed that out in our reply brief, and what I
18 show on [REDACTED]

19 [REDACTED] We have other ones.

20 [REDACTED]
21 [REDACTED]
22 You heard some testimony and discussion about Dr.
23 Reddy, one of Natco's fact witnesses. Dr. Reddy worked on the
24 development of the drug substance. So, you know, how do you
25 make a drug substance? He worked on that. He understood that

1 development process and the impurities and the compounds
2 present in that process and he testified to that. In fact, he
3 [REDACTED]
4 [REDACTED]
5 [REDACTED] that was not put into plaintiffs'
6 responsive brief. That was left out. That directly
7 contradicts their position. The data that's on top of slide
8 37, again, directly contradicts their infringement position.

9 But again, that's evidence relevant to infringement.
10 That's not claim construction extrinsic evidence. And the
11 fact that the patent describes ET-743, 745 and 770 as these
12 active anti-tumor compounds, these two facts in front of
13 plaintiffs caused them to go out and rewrite the claim. So
14 again, what we show here on slide 38 is taking the language of
15 single active anti-tumor compound, shuffling it up, and then
16 adding some more information there that really does a lot of
17 damage to the claim itself, but with the goal of trying to
18 cover the accused product.

19 So you'll see "a single" is still there but "compound"
20 is moved around. There's the words "providing the," has no
21 support in the intrinsic record. Not even sure what it means.
22 "Anti-tumor" is left, but then "active" is changed to
23 "activity." And then there's "of the composition." I'll walk
24 through why there's problems here in a minute. But again,
25 this is a complete claim rewrite in view of the accused

1 product, which the Federal Circuit again and again has told us
2 is improper.

3 So what this does, Your Honor, is in terms of
4 functional requirement of this thing, this active anti-tumor
5 compound, it now needs to provide something, provides the
6 activity of the composition. And what "of the composition" is
7 I'm not entirely sure, but that's what they say it does.

8 They also rely upon conclusory expert declaration to
9 report a requirement that impurities cannot be active
10 anti-tumor compounds. And then by rewriting the claim here
11 they broaden the claim to allow "single" to encompass multiple
12 compounds identified by the patent as active anti-tumor
13 compounds. Those include 745, 770 and others.

14 So that's -- before I get to slide 40 here, that's the
15 whole idea, the goal of their construction. To take the
16 accused product, rewrite the claims, and then try to cover the
17 product based on that.

18 Plaintiffs also rely upon -- heavily rely upon other
19 relevant extrinsic evidence. And the Federal Circuit, as
20 shown on slide 40 here, is telling us over and over again it
21 may be useful to the court, but it's unlikely to result in a
22 reliable interpretation of the claims scope unless considered
23 in the context of the extrinsic evidence.

24 And then the *C.R. Bard* case for the Federal Circuit
25 2004: Extrinsic evidence is generally less significant than

1 the intrinsic record in determining the legally operative
2 meaning of the disputed claim language.

3 So slide 41 is just a long listing. It's essentially a
4 laundry list of all the times that plaintiffs are relying
5 upon. What I've quoted here is extrinsic evidence because it
6 does include a lot of our accused product, which is not even
7 extrinsic evidence but there's very little substance when you
8 get to their arguments on extrinsic record. Really they're
9 trying to look at the accused product over and over again or
10 other extrinsic evidence to get into their claim rewrite.

11 And then the *Ruckus Wireless*, the Federal Circuit tells
12 us that legal error arises when a court relies upon extrinsic
13 evidence that contradicts intrinsic record. And that's
14 exactly what you see here and what plaintiffs are doing.
15 Their extrinsic evidence does, in fact, contradict the
16 intrinsic record.

17 Now let's talk about their extrinsic evidence. One of
18 those pieces of extrinsic evidence is their expert declaration
19 of Dr. Berkland. Now plaintiffs have now admitted that their
20 expert declaration is irrelevant to claim construction. They
21 state in their responsive brief that the only extrinsic
22 evidence relevant to this Court's claim construction is
23 analysis of Natco's representations regarding its ANDA
24 product. By default, by admission, they're saying their
25 expert declaration is at fault. We agree with that. We don't

1 think their expert declaration is relevant to claim
2 construction for several reasons.

3 As you see here on slide 44, in the *SkinMedica* case,
4 this is a pretty important case when it comes to expert
5 testimony. The Federal Circuit told us in 2013, expert
6 testimony, in particular, is less reliable because it's
7 generated at the time of and for the purpose of litigation and
8 thus can suffer from bias that's not present in the intrinsic
9 record. For that reason, conclusory, unsupported assertions
10 by experts as to the definition of a claim term are not useful
11 to a court. That's *SkinMedica* Federal Circuit 2013.

12 And that's exactly what we have here. In addition to
13 plaintiffs saying their own declaration isn't relevant to
14 claim construction, we don't think it is either. Dr.
15 Berkland's declaration was written a few months ago, October
16 2021. The patent was filed 15 years before, 2004. The
17 declaration is very conclusory. It really cites -- has very
18 few cites. It doesn't cite other publications for the time
19 about they might think or know. It just reaches a conclusion
20 and ultimately the declaration just parrots plaintiffs'
21 opening *Markman* brief. It has the same irrelevant extrinsic
22 evidence that plaintiffs relied upon. It's uses that accused
23 product to rewrite the disputed claim term here.

24 Now the other piece of extrinsic evidence that
25 plaintiffs rely upon is, and I say extrinsic evidence --

1 THE COURT: I want to make sure, Mr. Adams. Your
2 argument is that the plaintiffs have a declaration of their
3 expert, but then they're also admitting their expert
4 declaration is irrelevant?

5 MR. ADAMS: That's right, Your Honor.

6 THE COURT: Is that solely because of the language
7 that you cited to in their brief? I mean, look, I'm going to
8 ask Ms. Royzman on rebuttal whether she agrees with that. Is
9 that a practical position you want to take, that they decided
10 their expert's irrelevant?

11 MR. ADAMS: That's what they said. I certainly
12 didn't write their responsive brief or don't know what their
13 intent was, but that's what they said. Our position is that
14 it is irrelevant for the reasons I just talked about on slide
15 44.

16 THE COURT: All right. I'll ask her about it. But
17 okay.

18 MR. ADAMS: Plaintiffs have a discussion, they rely
19 upon Dr. Reddy's testimony. Again, that's -- that's really
20 not even extrinsic evidence, again, for claim construction
21 because it's not -- it's accused product they're really
22 talking about. You know, in the discussion before we filed
23 our reply brief plaintiffs admit that they're not relying upon
24 testimony of Dr. Reddy for purposes of claim construction.
25 Not to mention, as we point out in our reply, they're really

1 taken out of context. It's limited to a single table. We've
2 shown other data that they're actually -- just, they're wrong
3 on what is or isn't in the ANDA. But at the end of the day,
4 it doesn't matter for claim construction. The point is that
5 it's, again, looking at the accused product and not real
6 extrinsic evidence or the intrinsic record.

7 So for all those reasons, we don't think any of this
8 extrinsic evidence really supports plaintiffs' construction.

9 Now if you turn to the intrinsic record, I think in
10 some ways things get even worse when you start looking at the
11 claims themselves, when you start looking at the patent
12 specification and the file history to try to find support for
13 plaintiffs' construction.

14 Let's start with the claims as we do under *Phillips*.
15 Plaintiffs make the argument that they're rewriting -- that
16 they're construing the term "single active anti-tumor
17 compound" and it has support in the claims, but what they're
18 doing is rewriting the claims. So to say they have support
19 and then they rewrite it just doesn't -- is sort of circular.
20 But what happens when they rewrite the claims is they change
21 the dispute phrase from a noun to a verb and add some
22 functional requirement not found in the claims. And then the
23 terms used in plaintiffs' claim construction is also not found
24 in the claims elsewhere. And then ultimately what happens
25 with this claim rewrite is it raises more questions than it

1 really answers.

2 So if we look at slide 48 here, "a single active
3 anti-tumor compound" rewritten to the single compound
4 providing the anti-tumor activity of the composition. The
5 Federal Circuit has told us the claims -- the courts must
6 construe the claim as written, not as patentees wish they had
7 written it. And that's exactly what they're doing here is
8 rewriting the claims.

9 So what I want to focus on now a little bit is what we
10 really are left with after construction. The disputed phrase
11 is really -- it's a thing that you would place into a recipe
12 back in the kitchen, Your Honor. It's a formulation or
13 composition with something you put in there. Just like the
14 disaccharide is something you put in there. The active
15 anti-tumor compound is something you put in there. It's a
16 thing. A compound, you know, an active anti-tumor compound.
17 Plaintiffs' construction turned this thing, or noun, on to its
18 head. They turned this phrase into a verb. It's providing
19 the active -- the anti-tumor activity of the composition so
20 it's got to do something now with the function. So they turn
21 the noun, which is a thing, into a functional verb. It has to
22 do something.

23 And then in doing so, it really raises more questions
24 than it answers. This concept of providing -- they don't
25 explain what providing means. Providing to whom or to what?

1 Again, this isn't a method of treatment. This isn't even
2 limited to humans. I mean, this is a composition that you go
3 make in your lab and that's it. It really -- providing
4 doesn't -- no one knows what that means. It doesn't give any
5 context, to whom or to why or how is it providing. Plaintiffs
6 also don't explain why they change "active" to "activity"
7 other than it changes from a noun to a verb.

8 And then the last part "of the composition" really has
9 no support anywhere. "Of the composition." There are
10 numerous times throughout their briefing they'd say provide
11 the activity to the composition. Their construction says "of
12 the composition." Again, this has no support in the claim or
13 the intrinsic record at all, and it really raises a lot of
14 questions. What if there were a second compound? How do you
15 determine if it is providing "of the composition"? And that's
16 a question that no one can really answer.

17 So when you move on from the claims specification of
18 the '557 patent, things don't really get any better for
19 plaintiffs' construction. The phrase itself, a single
20 compound providing the anti-tumor activity, "the composition,"
21 that's not found in the specification. The word "providing"
22 is not used in specification regarding this disputed term,
23 "single active anti-tumor compound." Plaintiffs' functional
24 claim requirement that's now been included in, again, that's
25 not in the specification. There's no guidance as to what that

1 means, how it provides, how much is required to provide.
2 Provide to whom or to what? And then there's a discussion of
3 single active anti-tumor compound being active pharmaceutical
4 ingredient or API.

5 One of the questions Your Honor asked earlier about the
6 labeling of a product to Mr. Williams was a regulatory
7 question. There's a lot of regulatory questions that are
8 involved. That's not a patent question. That's a regulatory
9 question of what the FDA may do. Same thing with how do you
10 characterize what's in your product? You have to tell the FDA
11 based on a big book of regulations what's our product? How
12 much is in there? There are times when the FDA doesn't even
13 require you to identify it. It's at a certain level. So
14 there may be regulatory questions, but those regulatory
15 questions are not what's in the patent. The patent describes
16 a composition of formulation. An active pharmaceutical
17 ingredient is very different than single active anti-tumor
18 compound is used in this patent. Again, that API is a
19 regulatory term. This is not API used in a treatment claim.
20 Again, it's not even limited to humans. This claim you just
21 made in the lab. So when we look at that specification, the
22 specification doesn't support plaintiffs' new construction.

23 And then finally we look at the prosecution history,
24 Your Honor, and we've seen this several times today, but the
25 single active anti-tumor compound, single means single. And I

1 think, you know, there's an argument that, oh, well, we only
2 meant to limit to this. But single means single. It can't
3 mean something more. And the Federal Circuit has told us in
4 the *Norian Corp* case in 2005, in such cases we have held
5 patentees to the scope of what they ultimately claim, we have
6 not allowed them to assert that claim should be interpreted as
7 if they had surrendered only what they had to. So whatever
8 their intent is now, single must be single, not one plus
9 another one.

10 Again, that was clear from the language that was used
11 by the applicants themselves. On slide 54, applicants' claims
12 would not encompass combinations of anti-tumor compounds.

13 So even in view of that intrinsic record, even in view
14 of the prosecution history, plaintiffs rewrite the claim, as
15 we see on slide 55, but in application it goes even further
16 because the language "single" when you apply plaintiffs'
17 construction of providing the anti-tumor activity of the
18 composition, they actually really don't even mean single, Your
19 Honor. Even though they say "single" they don't mean it. And
20 why I say that is plaintiffs contend that under their
21 construction, even if there are multiple active anti-tumor
22 compounds in there, the one that is providing the activity to
23 the composition or of the composition is the single active
24 ones. So if you have several, it really doesn't matter. What
25 they say is -- under the construction is that there must be

1 one that provides the anti-tumor activity of the composition.
2 And this really played out in the deposition of plaintiffs'
3 expert, Dr. Berkland. Now, he was asked to determine whether
4 a lyophilized composition with a one-to-one ratio. So you
5 took, you know, 50% of ET-745 and 50% of ET-743, which you had
6 two active anti-tumor compounds. Right? Under the
7 construction he doesn't know. He doesn't know. So I think
8 that's very telling that their construction of providing the
9 anti-tumor activity composition can't be right because, again,
10 it's reading out the language of "single."

11 So really what this leaves us with is a very ambiguous
12 term. The parties agree to address the definition down the
13 road, but what you see from this new claim rewrite is that no
14 one really understands what it means. Under plain meaning one
15 and only one is single. Under plaintiffs' construction one
16 plus any number of additional active anti-tumor compound, as
17 long as they do not provide the anti-tumor activity of
18 composition, or they're called impurities. And again, through
19 deposition of Dr. Berkland, we asked him questions about how
20 one could determine whether a compound, such as ET-745, is an
21 active anti-tumor compound such that it's providing these
22 anti-tumor activity of the composition. He couldn't answer
23 the question. I think that question is too broad to answer.
24 It relies upon a bunch of things. The type of cancer being
25 treated, what's being measured. The type of cancer being

1 treated is irrelevant and immaterial to the claim in front of
2 us. It's not a treatment claim. And so ultimately even Dr.
3 Berkland can't figure out how you apply this without reading
4 out the single limitation.

5 And then there's an argument that ET-701 is an impurity
6 and so somehow under defendants' construction that we are --
7 are wrong because ET-701 is an impurity and we somehow read
8 that out. Again, I mentioned this earlier today, that's
9 certainly not true. ET-701 is a different limitation in the
10 claim that's dealt with separately. And that's an impurity
11 that the patentees knew about, they tested it, and that was
12 part of the bargain with the patent office to get these
13 claims.

14 But if you buy into their impurity argument and you try
15 to understand their construction and how do you apply it,
16 again, a deposition from Dr. Berkland sort of solidifies
17 defendants' position, which is he could not answer whether you
18 take ET-745, present at 10%, whether that would be an
19 impurity. Is that a second single active anti-tumor compound?
20 Is that an impurity? You know, what about 20%? 50%? Is it
21 -- at what level does it start providing the anti-tumor
22 activity to the composition? It's certainly not clear from
23 the claims. It's not clear from the specification or
24 plaintiffs' construction. And Dr. Berkland didn't know
25 either.

1 And so what that really does is say that if their
2 construction is applied, it imports a bunch of ambiguity and
3 also later down that road that would require that these claims
4 are held invalid because they're indefinite. And the Federal
5 Circuit has told us that claims are invalid for indefiniteness
6 where a person of skill in the art could not determine the
7 bounds of claims. And that's exactly what you see here with
8 plaintiffs' construction. And Dr. Berkland, their own expert,
9 couldn't really understand that.

10 So, Your Honor, that's all I have on my initial
11 presentation, unless you have questions.

12 THE COURT: No. Thank you, Mr. Adams. That was
13 helpful.

14 Let me ask you guys this, though, before I break, and
15 will keep my word that we will take a ten-minute break before
16 hearing from Ms. Royzman on a reply or rebuttal. Are we
17 marking these decks as exhibits to this hearing? Have you
18 guys discussed that and what were you proposing I do with
19 these?

20 MR. ADAMS: We did discuss that, Your Honor. My
21 position would be these are demonstratives, not exhibits to
22 the claim construction briefing. The exhibits were obviously
23 submitted as declarations.

24 MS. ROYZMAN: We're fine either way, Your Honor.

25 THE COURT: Okay. I mean, there's no objection. So

1 you're not looking necessarily for me to mark these or
2 identify them as exhibits or attach them or anything like
3 that.

4 MS. ROYZMAN: No.

5 THE COURT: Okay. All right. Why don't I keep to my
6 word. You guys want to break for ten minutes and then just
7 kind of jump back on? I'll probably just stay on. I'll just
8 mute and knock out my video and take a break. But does that
9 work, Ms. Royzman, for you?

10 MS. ROYZMAN: Yes. Would 15 minutes be okay, Your
11 Honor, just for --

12 THE COURT: Absolutely fine. You tell me.

13 MS. ROYZMAN: That would be helpful.

14 THE COURT: It's a little after one. So we'll come
15 back a few minutes after quarter after.

16 MS. ROYZMAN: That's perfect. Thank you, Your Honor.

17 THE COURT: I'll see you guys in a bit.

18 MR. ADAMS: Thank you.

19 (A short recess occurred.)

20 THE COURT: We're back on record. I have two quick
21 questions, but do you guys want to do this rebuttal first?
22 Even though it better be quick, but I'll give you guys a few
23 minutes to say your peace, but I had two quick questions.

24 Ms. Royzman, what's your preference? I don't want to
25 cut off your flow if you're ready to give Mr. Adams a punch.

1 MS. ROYZMAN: Your Honor, I'm happy to address your
2 questions first.

3 THE COURT: Here's my first question, and I'll tell
4 you, both are tailored to making you guys do as much work as
5 you need to and me do less. Here's my first question. My
6 understanding is that the construction that I'm being asked to
7 apply, it's single active anti-tumor compound, right? It's a
8 single active anti-tumor compound. My question is, can the
9 parties agree on what "single" means? Meaning can I reduce
10 the term to active anti-tumor compounds? Or are you guys even
11 disputing what "a single" would mean within that term? Do you
12 understand my question? I'm trying to figure out whether we
13 can reduce the actual term to active anti-tumor compound
14 because both plaintiff and defendants are in agreement on what
15 the word "a" and "single" mean.

16 Do you have a response to that, Ms. Royzman? I just
17 want to get your sense of it. If your answer is you guys are
18 fighting over "single," then I'll back off, but I'm trying to
19 reduce what I need to look at.

20 MS. ROYZMAN: Yeah. I think, Your Honor, I mean, I
21 think it's important for, you know, for the context, but I
22 don't think there's a dispute with respect to -- I think that
23 phrase is important, but I don't think there's a dispute as to
24 the meaning of "a" or "single." And I think one of my slides
25 had reflected that.

1 And so I think that's fair, but I think the phrase is
2 -- the overall phrase is important and probably should stay as
3 is, but I don't think Your Honor has to construe "a single"
4 because there's no dispute as to -- as to that meaning
5 whatsoever.

6 THE COURT: Mr. Adams, what's your take? Are you
7 disputing that? I don't mind keeping that in, but are you
8 disputing what "a single" would mean with respect to
9 plaintiffs? It doesn't sound like they're fighting over it,
10 but I don't know.

11 MR. ADAMS: Your Honor, I don't think we dispute what
12 "a single" means. I think it means one. I think the phrase
13 as a whole was added during the prosecution as a phrase,
14 single anti-tumor compound. So I think that phrase as a whole
15 has a specific meaning in the context of the entire intrinsic
16 record. So I think that's why the parties brought that up
17 originally for construction. So I think in view of that, even
18 though we don't dispute what "single" means, we think single
19 means one, I think the phrase as a whole, it's really the crux
20 of the issue.

21 THE COURT: I will tell you what. Based on both your
22 responses, which I think are consistent with each other, so it
23 sounds like you're in agreement, I'm not looking to cut out "a
24 single," but at the same time on the record it's my
25 understanding that you're not actually disputing, though, the

1 meaning of the term "single," but you'd like to keep it within
2 the term for purposes of construction, correct?

3 MS. ROYZMAN: That's correct, Your Honor.

4 THE COURT: Let me switch to a second question. This
5 has to deal with extrinsic evidence, and I will again pose
6 this question to both of you. Look, my experience in a
7 *Markman* is limited based on my past life and even now as my
8 recent elevation, but I've seen this before with other
9 district judges so I thought I might as well propose it here
10 and get a sense from at least the parties in this specific
11 case when I need to delve into extrinsic evidence.

12 Say, for example, I agree with plaintiffs that the
13 plain and ordinary meaning apply and no construction is
14 necessary. In that content, would I still need to delve
15 outside of the claim, the specification, the prosecutorial
16 history, and delve into extrinsic evidence, or would that not
17 be necessary? Or if it doesn't matter what I do in this case,
18 I have to delve into that? This is, again, just how much work
19 do I need to do and how many different sources do I have to
20 analyze?

21 MS. ROYZMAN: I think Your Honor could resolve this
22 claim construction dispute based on the intrinsic evidence.
23 And so I don't think you need to delve into it other than to
24 the extent Your Honor finds it helpful. And, you know, so the
25 expert declaration talks about impurities and it discusses --

1 part of the reason it doesn't have a whole variety of other
2 citations is because it really discusses the intrinsic
3 evidence. But Your Honor could decide the claim construction
4 issue just based on the -- on the intrinsic evidence, and
5 courts often do.

6 THE COURT: Mr. Adams, where are you on that?

7 MR. ADAMS: My position is shockingly similar to Ms.
8 Royzman's. I agree the intrinsic record. You can get into
9 the construction here based on the intrinsic record alone. I
10 don't think you have to go to any of the extrinsic evidence
11 that's in front of Your Honor.

12 THE COURT: All right. Is that something I can -- so
13 if I do this analysis and I deal simply with the intrinsic
14 evidence, the claim specification, the prosecutorial history,
15 do I have the parties' agreement that I don't need to delve
16 into intrinsic evidence for purposes of resolving this
17 dispute? Because that's what I'm going to put no matter which
18 way I go. I am just trying to figure out whether it's
19 necessary for either side. I'm not so sure it benefits either
20 of you, and I don't think anyone's prejudiced, but I want to
21 make sure that we're clear on the record.

22 MR. ADAMS: You certainly have the defendants'
23 agreement to that, Your Honor.

24 THE COURT: Ms. Royzman?

25 MS. ROYZMAN: Your Honor, and you have ours. I

1 think, you know, it should only be consulted to the extent
2 it's helpful to Your Honor. That was the intent of it.

3 THE COURT: All right. I appreciate that from both
4 of you.

5 Those were my only two questions. Like I said, I'll
6 keep the term the way you guys have provided it as "a single
7 active anti-tumor compound." That's the term before me, so I
8 won't be reducing it, but my understanding is the term "a
9 single" is not actually in dispute, at least the meaning of
10 that word is not in dispute. My other understanding is that I
11 will move forward, and regardless of my analysis, I will be
12 reviewing intrinsic evidence only, which is in agreement by
13 the parties; that I do not need to delve into extrinsic
14 evidence unless the Court deemed that it might be helpful to
15 me.

16 That being said, Ms. Royzman, I appreciate it. I'm
17 sorry for the delay. How much time are we looking at here?
18 Because I know Mr. Adams is going to want to have his last
19 word, and I don't want to go back and forth. How long are we
20 doing this?

21 MS. ROYZMAN: I think it should be fairly, fairly
22 quick; maybe ten minutes or so.

23 THE COURT: All right.

24 Mr. Adams, I'll allot you around the same amount of
25 time. Let's keep it fairly tight.

1 Ms. Royzman, I'm happy to hear from you in response to
2 Mr. Adams' presentation. You've got the Court's attention.

3 MS. ROYZMAN: Thank you, Your Honor.

4 So Mr. Adams started with the local rules, and again,
5 we find that surprising, but there are obviously no violations
6 of the local rules. Judge Goodman considered that and
7 rejected defendants' arguments. There was back-and-forth.
8 The back-and-forth resolved a lot of the claim construction
9 disputes. The parties better understood each other's
10 positions. We elaborated on our ordinary and plain meaning in
11 view of our, you know, at that point full understanding of
12 what defendants intended with their construction, which is
13 very hard to -- very hard to understand so that's on the local
14 rules. There's no rewrite of any kind.

15 Then slide 37 that was put up by Mr. Adams, this was a
16 slide or an image from the reply brief that that's -- that's
17 incorrect and out of context from start to finish, and we
18 tried to provide that context in our proposed reply brief,
19 which is DI-181.

20 Now I'd like to pull up columns 7 and 8 of the patent.
21 Dan Williams will help with that. He's got much better
22 technical skills.

23 And so I think, Your Honor -- because defendants'
24 briefing did describe ET-745 and ET-770 as "particularly
25 preferred" in their brief, that surprised us, and Your Honor

1 asked a question about it. And what column 7 and 8 made clear
2 is there's a list of preferred compounds, and ET-743 is listed
3 first. The one other one, I guess, that's at issue here is
4 ET-745, and it's described as "preferred" here. And then it
5 states -- and here's where the "particularly preferred"
6 language comes from -- it's right here immediately below
7 ET-743, also known as ET-743 or ecteinascidin. 743
8 particularly preferred.

9 And then the specification continues to focus on ET-743
10 because those are really the formulations that are at issue in
11 the claims and at issue here. We are not dealing with ET-745
12 compositions or ET-770 or any other ET compound. And so we
13 have a summary of that.

14 Dan, could you pull that up? Sorry, Dan. Maybe slide
15 2, ET-743 formulations.

16 In the context of the claimed invention, in the context
17 of the claims, ET-745 and ET-770 simply are not actives.
18 ET-743 is the particularly preferred compound of the
19 invention. That's in column 8, what we just looked at. All
20 of the examples are ET-743 formulations. There are no ET-745
21 or ET-770 embodiments or examples. There's no formulation
22 where either compound is the active compound. There are no
23 claims with ET-745 or ET-770 as an active compound. These are
24 potential impurities of ET-743 formulations, i.e., formulations
25 where ET-743 is the active compound. These are only

1 impurities in the context of the claimed invention, which is
2 really all that's relevant here.

3 Can we go back to the patent, Dan. Could you pull up
4 column 27.

5 Your Honor, and so here, in column 27, it's -- one,
6 it's made very clear that formulation ET-NF-G is a preferred
7 formulation. That's the ET-743 formulation that's described
8 this way.

9 And then immediately below, contrary to statements from
10 Natco from Mr. Adams about testing, or whatever, it's very
11 clear, embodiments of formulation, according to this
12 invention, were tested after storage under a plurality of
13 conditions, and total impurities, including potential ET-701
14 and potential ET-745 and potential other ET compounds, other
15 compounds did not exceed a certain percentage after nine
16 months. That's just made very clear.

17 So this is not just about ET-701. The patent is clear
18 that there are potentially a whole variety of impurities, and
19 they have been reduced by the unique formulation that the
20 defendant -- that the plaintiffs came up with -- that the
21 inventors came up with.

22 And if you look at the claims, all of the claims are
23 to, again, ET-743 formulations. They are not formulations of
24 other things, and they reference the main impurity. Okay.

25 So Natco's construction, and Mr. Adams talked about

1 this, he said, well, maybe, you know, maybe it excludes some
2 embodiments, but that's okay. ET-NF-G is a preferred
3 formulation, and the construction proposed by defendants and
4 their theory as to its meaning wouldn't just read out ET-NF-G,
5 which actually is specifically claimed in claim 15, if Your
6 Honor can see in claim 15, you have the exact amounts. And so
7 I don't know what Mr. Adams was talking about when he said the
8 claims don't provide particular amounts. Some of the claims
9 don't recite amounts, others do. But it's very clear that the
10 proposed construction and defendants' theory would turn the
11 patent into a complete nullity. It would read every
12 embodiment out of every claim, including the embodiment that
13 Natco and Sun copied exactly.

14 Now, Mr. Adams made a number of critical admissions
15 during his presentation that I'd like to flag for Your Honor.
16 First, he said the claims are narrowly drafted, and we agree.
17 The claims are narrowly drafted. They are to ET-743
18 compositions. They're not to other compositions. And ET-743
19 compositions, as immediately stated above the claims, can have
20 certain impurities.

21 He also admitted -- and I'd like to pull up our slide
22 crossing out "active." But he admitted quite expressly that
23 the construction that's proposed by defendants reads out
24 "active" because it does. Because they're equating a single
25 active anti-tumor compound with anti-tumor compound. It's

1 just wrong. It's clear error. It's an admission of clear
2 error.

3 And then he also admitted that the active anti-tumor
4 component, the active anti-tumor compound is the thing you put
5 into the formulation. Well, we agree. It is the thing that
6 you put into the formulation. It's the active. It's ET-743.
7 And the inevitable potential impurities result from that
8 active, not separately. The only active that's put into the
9 composition is ET-743. And plaintiffs' construction, the
10 alternative construction or elaboration on the plain and
11 ordinary meaning isn't functional, isn't doing anything
12 functional. It's a thing. An active is a thing that provides
13 anti-tumor activity. That's what it does. Here we have an
14 anti-tumor composition, and the addition of "composition" was
15 highly important and joins issue because defendants have
16 stripped possessing properties from the composition. And they
17 have to because they're relying on the alleged impurities in
18 support of their non-infringement position. That's -- that's
19 what they're doing and that's -- that's the -- that's the
20 explanation.

21 So I think that's largely it, Your Honor. We are --
22 the case law makes clear that it's important for the Court to
23 understand the dispute and that the accused product and
24 defendants' infringement theories are critical to
25 understanding that dispute. And plaintiffs are not relying on

1 the accused device to supply any claim limitations. They are
2 using the accused device to provide an understanding of the
3 actual dispute. And that's -- that's all that's -- that's all
4 that's happened here, and they think that's -- that's
5 essential.

6 So in -- in sum, the Court should adopt the ordinary
7 meaning based on the intrinsic evidence or the construction
8 that that's -- that's proposed by plaintiffs, which just
9 elaborates on the ordinary -- on that ordinary meaning of what
10 "an active" is, what an active anti-tumor compound is in the
11 context of that claim.

12 Thank you, Your Honor.

13 THE COURT: Sorry. Thank you. I was on mute.

14 Mr. Adams, do you want a few minutes?

15 MR. ADAMS: I do. Thank you, Your Honor. I'll be
16 really brief here.

17 I want to first start with -- I think it was the
18 question you asked about "preferred," "particularly preferred"
19 in our briefing and rebuttal to Ms. Royzman.

20 If I can share my screen here, I have traced that back
21 to the patent. So it is there. I wasn't wrong. But let me
22 just share this screen here. If we go to column 7 -- give me
23 a second to get there. If we go to column 7, lines 4 and 5,
24 this is where that language comes from. Compounds following
25 formula 3 are particularly preferred. It's a generic compound

1 here and it has different R groups. Those R groups are
2 attached. Here is one, R-21. This is what leads us to ET-745
3 and ET-770. So I think our language "particularly preferred"
4 with a compound is actually correct and supported by column 7,
5 lines 4 and 5, of the patent.

6 The next point I want to make is really Ms. Royzman
7 talked about column 27 and how somehow we were reading out
8 this -- this -- the preferred embodiment of ET-NF-G, and as I
9 understand the argument, I think what she's saying is ET --
10 EFT(sic) has impurities of something more than ET-701, and
11 that's simply not true.

12 If we go the data in the patent, again, all the data
13 that's presented in the patent for ET-NF-G -- sorry for the
14 scrolling, Your Honor. Let me get to it. The data is right
15 here. Look at this table. The table in front of you, Your
16 Honor. This is formulation ET-NF-G, has impurity -- and I'm
17 looking at column 27 here around line 20 through 25. ET-NF-G
18 has purity data. It goes up to three months. There's no
19 ET-701 data here. There's no ET-745 or some other ET compound
20 data other than ET-743. So this concept that ET-NF-G is
21 somehow read out by our construction, that is simply just not
22 true. There's no data of ET-745 present. And the language
23 that kept coming up over and over, it comes from column 27
24 around line 37. Embodiments of formulations according to this
25 invention were tested.

1 It doesn't say -- it goes on to mention ET-745 here.
2 That's the only time ET-745 is mentioned in this patent other
3 than to talk about it as a preferred compound of the
4 invention. It shows it one time here. But this section
5 doesn't show any data of any specific formulation. Certainly
6 not ET-NF-G. And it doesn't say every embodiment, preferred
7 embodiments. It simply says embodiments of formulations
8 according to the invention. And that claim is -- you know,
9 patentees use when they're talking about something they did
10 here. It's not saying every single thing we tested had this
11 ET-745. It's simply saying that we tested some. These were
12 tested out at nine months.

13 If we look at column 27, line 46 here, I've highlighted
14 on the screen. This is nine months. The claims talk about
15 three months, claim 1, claim 22. This isn't even within the
16 scope of the claim. The claim is at three months. This data
17 it's talking about is not of every formulation. It doesn't
18 even tell us what the data is for ET-745. It's not about the
19 preferred embodiment of the claim because ET-745 isn't
20 mentioned in the claim. It's also at nine months. It's
21 nothing to do with the claims at three months. At best, it's
22 a different embodiment that's even claimed in any of the
23 claims because it's at nine months.

24 So the argument used in this information right here on
25 ET-NF-G, the argument we're somehow reading out embodiments or

1 preferred embodiments, is simply not true.

2 Now, the next point I want to make is -- I just heard I
3 made some admissions. I obviously disagree with those. I
4 think one of the arguments is that we admitted that we were
5 reading out the word "active." Again, that's simply not true.
6 I think we said over and over again that we construed the
7 claim term, "active anti-tumor compound," we construed that to
8 possessing anti-tumor properties. We're providing those
9 construction words. We're not reading out the word "active."

10 Then the last point I want to make is the -- you heard
11 a discussion there at the end about the accused embodiments.
12 I thought we just agreed we're not going to have Your Honor
13 rely on intrinsic evidence, so I will say none of that is
14 relevant. It's, again, not intrinsic evidence. It's the
15 accused product.

16 But no matter how you slice this, at the end of the
17 day, these claims require single active anti-tumor compound.
18 The whole alleged invention was about minimizing the impurity
19 ET-701. Yet under plaintiffs' construction with single active
20 anti-tumor compound allowing other things like ET-745, 770, or
21 who knows what else, it just doesn't make sense that you can
22 -- you need to limit ET-701 to less than 2%, that's what the
23 claim requires, what this whole idea was about. Yet under the
24 construction of providing, you can have any amount of what
25 they call impurities. You can have 20% of ET-745 under their

1 construction and it still would be covered by single active
2 anti-tumor compound under their construction. That simply
3 cannot be correct.

4 So regardless of what's in our product, regardless of
5 that analysis of the accused product, plaintiffs' construction
6 cannot be correct based on that simple principle that it
7 requires single active anti-tumor compound.

8 That's all I have, Your Honor.

9 THE COURT: All right. Well, thank you, Mr. Adams.
10 I don't know if we can take off the document or not,
11 although I don't know if we need it.

12 First of all, thank you, counsel, Ms. Royzman and Mr.
13 Adams, and I think Mr. Williams also. I know he presented on
14 the technology early on, so I want to thank him for his
15 presentation. I can see Charlie Lizza and Bill Baton sitting
16 patiently waiting for me to get to my lunch or sign off.

17 I'll take your tutorial under advisement. I've got all
18 the briefs, so I think the issue is now back in my lap.

19 Is there anything more that we need to discuss, Ms.
20 Royzman? From the plaintiffs' perspective, is there anything
21 additional that we need to talk about today, whether related
22 to this claim or not, while I have you on? Otherwise, I'm
23 going to go to Mr. Adams and I'm going to adjourn for the day,
24 but anything from plaintiff?

25 MS. ROYZMAN: No. Thank you, Your Honor. Thank you

1 for your attention.

2 THE COURT: Thank you for your time.

3 Mr. Adams, anything on your end that we need to
4 address? Otherwise, the issue is with me.

5 MR. ADAMS: Nothing else from defendants, Your Honor.
6 Thank you for your time.

7 THE COURT: What about your codefendant? Somebody is
8 on here. Mr. Miller, anything on your end?

9 MR. RICHTER: Your Honor, I think that's us, and I
10 don't believe so, no.

11 THE COURT: Everybody, I hope you had a wonderful New
12 Year's. I've got some work to do this on this case ahead of
13 me, so let me let you all go. It was nice seeing all of you
14 and hopefully at some point later in 2022 we'll be doing this
15 in person, but for now this is the new world order over here.
16 So nice seeing everybody. Be safe. Take care.

17 MS. ROYZMAN: Thank you, Your Honor.

18 MR. ADAMS: Thank you, Your Honor.

19 (Court concludes at 1:47 p.m.)

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1 FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE.

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4 I certify that the foregoing is a correct transcript from
5 the record of proceedings in the above-entitled matter.

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11 /S/ Megan McKay-Soule, RMR, CRR January 11, 2022

12 Court Reporter Date

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